## COMMISSION STAFF WORKING DOCUMENT

## Annex to the:

## REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

Fifth Report on the Statistics on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union
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## I. INTRODUCTION

The objective of this report is to present to the Council and the European Parliament, in accordance with Article 26 of Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes ${ }^{1}$, the statistical data on the number of animals used for experimental and other scientific purposes in the Member States of the EU.

The first two statistical reports published in $1994^{2}$ and $1999^{3}$ covering data on experimental animals collected in 1991 and 1996 respectively provided a limited amount of statistical analysis due to the absence of a consistent system of reporting the data on the use of experimental animals in the Member States. In 1997 an agreement was reached between the competent authorities of the Member States and the Commission to submit data for the future reports under a format of eight harmonized tables. The third and the fourth statistical reports published in $2003^{4}$ and $2005^{5}$ covering data collected in 1999 and 2002 were based on these agreed harmonized tables. This allowed a much wider interpretation of the results on the use of experimental animals in the EU. In spite of the progress made in the content of these two last statistical reports, it ought to be stressed that there were some inconsistencies in the data submitted by the Member States and also that in all cases except the report of 2003, one Member State collected data from another year.

This Fifth Statistical Report covers for the first time data collected by 25 Member States as a result of the accession of 10 new Member States in 2005. It gives an overview of the year 2005 with the exception of one Member State who reported data of 2004.

The Commission Staff Working Document accompanies the "Report from the Commission to the Council and the European Parliament - Fifth Report on the Number of Animals used for Experimental and other Scientific Purposes in the Member States of the European Union". The report summarizes the data and conclusions presented in this Staff Working Document.

[^0]
## II. DATA SUBMITTED AND GENERAL ASSESSMENT

## II.1. Data submitted by the Member States

All 25 Member States submitted the data in the agreed EU format.
Regarding the quality of data, in most cases, Member States have applied a quality control check on the set of data submitted for 2005. This exercise was the first for the 10 new Member States (EU 10), and in general the coherence of the data has greatly improved for the other Member States.

The quality check of the data submitted by the Member States is essentially governed by four criteria based on certain relationship between the data in the different tables.

- The first of these relationships is the total number of animals used by species, column 1.2 of EU Table 1, which is broken down into purposes of experiments in EU Table 2. Thus, the totals of the Tables 1 and 2 should be identical.
- The second relationship concerns column 2.6 of EU Table 2 "animals used for toxicological and other safety evaluation" which is broken down into types of products/endpoints, EU Table 3, into Regulatory requirements, EU Table 6, and into types of toxicological tests, EU Table 7. The total at the bottom of column 2.6 must be equal to the total at the bottom of table 3,6 and 7 .
- The third relationship is that the sum of column 2.4 and 2.5 of EU Table 2 must be equal to the total of EU Table 5.
- In the fourth relationship, the total row of EU table 3 "animals used for toxicological and other safety evaluation by types of products" should be equal to the total of table 8 .

For the present report it was generally considered that the quality criteria had sufficiently been respected to allow an analysis at European level of all eight EU tables.

## II.2. General assessment

Each Member State is requested, pursuant to Articles 13 of Directive 86/609/EEC, to submit to the Commission the statistical data on the animals used for experimental and other scientific purposes. The data covers the year 2005 with the exception of France who reported on the year 2004. Malta has reported no animal use in 2005.

Council Resolution 86/C331/02 of the representatives of the Governments of the Member States of the European Communities, meeting within the Council of 24 November 1986 regarding the protection of animals used for experimental and other scientific purposes ${ }^{6}$ allows the use of animals in experiments for education and training, but where the purposes of such experiments are not covered by the Directive i.e. they are not experimental or scientific in the sense of the Directive, Member States will according to the Resolution apply national provisions which are no less severe than those of the Directive. Therefore, a number of Member States have also included animals covered by the Resolution in the report.

[^1]The first part of this report aims at providing a comprehensive overview on the numbers of animals used for various experimental purposes in the Community in 2005. The analysis will look at the purposes of the use of animals. Some of these purposes will be broken down further into more precise parameters. It will also look at the different legislative requirements regarding the use of experimental animals and also the type of testing carried out on the different species of animals. For the first time the analysis will cover all eight tables submitted by the Member States in 2005.

Because 10 new Member States are reporting data for the first time it will not be possible to draw conclusions on the evolution of the use of animals for experimental purposed in the EU by comparing data with those of the previous reports. However, some comparisons in trends will be attempted and significant changes in use will be highlighted in the report.

The number of animals used in the 10 new Member States (EU 10) represents $8,6 \%$ of the total number of animals used in the 25 Member States (EU 25). Therefore, when any of the categories reported in the different areas show a significant increase or decrease beyond the $8,6 \%$, this will be highlighted in the report

In addition, in the first chapter of this report, Table 1bis with the data of EU 15 and Table 1 tris with the data of EU 10 have been prepared to see the effects of the new Member States on the EU statistics. Furthermore, an attempt will be made to compare the results of the total number of animals used in 2005 within the "old" EU 15 with those submitted for the pervious reports.

The second part of this report provides the individual data from the Member States together with their respective comments and interpretations.

In the EU, the total number of animals used for experimental and other scientific purposes in 2005 in the 25 Member States amounts to 12,1 million (with data from France of 2004).

As in previous reports rodents together with rabbits represent almost $78 \%$ of the total number of animals used in the EU. Mice are by far the most commonly used species covering $53 \%$ of the total use, followed by rats with $19 \%$.

The second most used group of animals was, as in previous years, cold-blooded animals representing $15 \%$. The third biggest group of animals was birds with a little over $5 \%$ of the total use.

As in 2002, no Great Apes were used in experiments in the EU in 2005.

## II.3. Structure of the Report

The report is divided into two parts:
A A global compilation and overview for the European Union of the statistical data of the Member States for 2005.

A consolidated table has been computed on the basis of the data submitted by the Member States for each EU Table and is presented at the end of each chapter. Each table is illustrated by a graphical presentation to give a more readable overview of the EU situation.

Similarly to what happened in 2002, the complete data for 2005 include statistics from the year 2004 in France. Therefore, the totals used in this report are a mixture of years. Comparisons were nevertheless made on this basis since no other data were available.

The reader is invited to take note that the numbering of tables and graphical presentation in Part A of the report are linked to the numbers of the EU Tables and not to the numbering of the chapters of the report.

B The data submitted by each Member State with a summary of the Member State's comments.

## PART A: COMPILATION AND OVERVIEW OF THE DATA OF 2005

## III.1. Results of EU Table 1: $\underline{\text { Species and number of animals }}$

Two types of information can be drawn from the data submitted by the Member States in EU Table 1. The first is relating to the total number of animals used subdivided into 25 species by the Member States. The second is relating to the place of origin of the animals used for experimental or other scientific purposes.
III.1.1. The data on the total number of animals used in the MS

Table 1.1 of this report presents the consolidated data on the number of animals used for experimental purposes, by species, submitted by 25 Member States. Since the previous report of 2002, Table 1.1 includes the data on the number of animals used also in the 10 new Member States.

Malta informed the Commission that no animal experiments were carried out in their country in 2005.

The total number of animals used in 2005 (France reporting for 2004) in the 25 Member States (EU 25) amounts to 12.1 million animals. It is important to note that the number of animals used in the 10 new Member States (EU 10) represents $8,6 \%$ of the total number of animals in the EU 25 . This proportion will be used as the basis to highlight any changes in trends which significantly deviate from it.
III.1.2. Treatment and interpretation of the data of Table 1.1

In order to present an overall evaluation and subsequently a graphical analysis, animals were grouped in classes. The result of this exercise is presented in Table 1.2 at the end of this chapter. Table 1.2 is illustrated by Figure 1.1.

Figure 1.1
Percentages of animals used by classes by the reporting Member States


Rodents together with rabbits represent $77,5 \%$ of the total number of animals used. Within the rodents class, mice $(53 \%)$ and rats ( $19 \%$ ) are by far the most used species.

The second most used group is represented by cold-blooded animals with $15 \%$.
Birds is the next highest animal group being used for experimental purposes with 5,4\%
The Artio and Perissodactyla group including horses, donkeys and crossbreeds (Perrisodactyla), pigs, goats, sheep and cattle (Artiodactyla) represent only $1,1 \%$ of the total number of animals used in the Member States.

Carnivores represent $0,3 \%$ of the total number of animals used and non-human primates represent $0,1 \%$ of the animals used in 2005.

## III.1.3. Comparison with the data of the previous reports

In this chapter, and the following chapters dealing with comparisons, the reader is invited to take note of the fact that in 1996, in 2002 and 2005 one Member State (France) has reported data respectively for 1997, for 2001 and 2004. Nevertheless, assuming that fluctuations in the annual numbers of animals used per species in a country are limited, it is possible to make semi-quantitative estimates of the observed trends by comparing changes in proportions of use, expressed in percent.

## Comparison between proportions of classes of animals used in 1996, 1999 2002 and 2005

| Class of species | $1996\left(^{*}\right)$ | 1999 | 2002 (**) $^{2005(* * *)}$ |  |
| :--- | :---: | :---: | :---: | :---: |
| \% Rodents-rabbits | 81,3 | 86,9 | 78,0 | 77,5 |
| \% Cold-blooded animals | 12,9 | 6,6 | 15,4 | 15, |
| \% Birds |  | 4,7 | 5 | 5,4 |
| \% Artio Perissodactyla |  | 1,2 | 1,2 | 1,1 |

(*) 14 Member States reporting for 1996, one for 1997
(**) 14 Member States reporting for 2002, one for 2001
(***) 24 Member States reporting for 2005, one for 2004
In overall, the percentages of rodents and rabbits show some fluctuation around $80 \%$. For cold-blooded animals the proportion used in 1996, in 2002 and 2005 is between 10 to $15 \%$ but a much lower use of 6,6\% was observed in 1999 .

Birds representing the third largest percentage of animal used, varies between 4 to $5 \%$. The group of artio and perissodactyla fluctuates around $1 \%$.

The inclusion of the data of the new Member States (EU 10) should in principle increase the actual numbers of animals of each species with the magnitude of around $8,6 \%$. However, the use of some species has decreased compared to the 2002 report. This is illustrated in Table 1.0 below.

Three other columns were included in Table 1.0 to show the change between 2002 and 2005 among EU 15, and to further analyse the changes in total numbers. More substantial overall changes have been highlighted and in particular any changes among EU 15 contrary to the overall change.

Table 1.0: Changes in species number and proportion between 2002 and 2005

| Species | Animal numbers in EU 25 2005 | Animal numbers in EU 15 2002 | $\begin{aligned} & \hline \text { Change } \\ & \text { since } \\ & 2002 \end{aligned}$ | \%chan ge since 2002 | Animal numbers in EU 15 2005 | $\begin{aligned} & \hline \text { Change } \\ & \text { since } \\ & 2002 \\ & \text { in EU } 15 \end{aligned}$ | \%chan ge since 2002 in EU 15 |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a Mice (Mus musculus) | 6430346 | 5459729 | 970617 | 17,8 | 6038846 | 579117 | 10,6 |
| 1.b Rats (Rattus norvegicus) | 2336032 | 2311344 | 24688 | 1,1 | 2130446 | -180898 | -7,8 |
| 1.c Guinea-Pigs (Cavia porcellus) | 257307 | 226339 | 30968 | 13,7 | 233180 | 6841 | 3,0 |
| 1.d Hamsters (Mesocricetus) | 31535 | 52382 | -20847 | -39,8 | 30935 | -21447 | -40,9 |
| 1.e Other Rodents (other Rodentia) | 64474 | 58827 | 5647 | 9,6 | 47451 | -11376 | -19,3 |
| 1.f Rabbits (Oryctolagus cuniculus) | 312681 | 267675 | 45006 | 16,8 | 293156 | 25481 | 9,5 |
| 1.g Cats (Felis catus) | 3898 | 3808 | 90 | 2,4 | 3624 | -184 | -4,8 |
| 1.h Dogs (Canis familiaris) | 24119 | 21116 | 3003 | 14,2 | 22010 | 894 | 4,2 |
| 1.i Ferrets (Mustela putorius furo) | 2690 | 2078 | 612 | 29,4 | 2512 | 434 | 20,1 |
| 1.j Other Carnivores | 8711 | 3110 | 5601 | 180,1 | 1734 | -1376 | -44,2 |
| 1.k Horses, donkeys and cross breds (Equidae) | 5312 | 4677 | 635 | 13,6 | 4310 | -367 | -7,8 |
| 1.I Pigs (Sus) | 66305 | 61164 | 5141 | 8,4 | 56657 | -4507 | -7,4 |
| 1.m Goats (Capra) | 2146 | 3016 | -870 | -28,8 | 1958 | -1058 | -35,1 |
| 1.n Sheep (Ovis) | 30021 | 30979 | -958 | -3,1 | 26840 | -4139 | -13,4 |
| $1.0 \quad$ Cattle (Bos) | 36271 | 26569 | 9702 | 36,5 | 21694 | -4875 | -18,3 |
| 1.p Prosimians (Prosimia) | 677 | 1095 | -418 | -38,2 | 677 | -418 | -38,2 |
| 1.q New World Monkeys (Ceboidea) | 1564 | 1192 | 372 | 31,2 | 1564 | 372 | 31,2 |
| 1.r Old World Monkeys (Cercopithecoidea) | 8208 | 8075 | 133 | 1,6 | 8151 | 76 | 0,9 |
| 1.s Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t Other Mammals (other Mammalia) | 9950 | 3618 | 6332 | 175,0 | 4701 | 1083 | 29,9 |
| 1.u Quail (Coturnix coturnix) | 9246 | 12984 | -3738 | -28,8 | 7212 | -5772 | -44,4 |
| 1.v Other birds (other Aves) | 649813 | 521983 | 127830 | 24,5 | 445281 | -76702 | -14,7 |
| 1.w Reptiles (Reptilia) | 2477 | 3168 | -691 | -21,8 | 853 | -2315 | -73,1 |
| 1.x Amphibians (Amphibia) | 74620 | 59689 | 14931 | 25,0 | 59402 | -287 | -0,5 |
| 1.y Fish (Pisces) | 1749178 | 1586403 | 162775 | 10,3 | 1627103 | 40700 | 2,6 |
| 1.z TOTAL | 12117583 | 10731020 | 1386563 | 12,9 | 11070299 | 339279 | 3,2 |

The total number of hamsters, goats, prosimians, quail and reptiles have all decreased from $40 \%$ to $22 \%$.

The biggest percentual change has, however, been noted in the increase of the use of other carnivores. This increase is essentially due to the addition of data from the new Member States (see Table 1.0) although these species are not used in great numbers (from 3110 to 8711). This is further contrasted against a decrease in their use in EU 15. The other large increase both in EU 25 and also in EU 15 is for the use of other mammals ( 3618 to 9950).

One new Member State reported significant use of 'other carnivores', 'other mammals', cattle, 'other rodents', quails and horses, pigs and other birds, in comparison with other Member States. This was attributed to wildlife and environmental research studies in that specific geographical location, and testing in the areas of agricultural and animal breeding specific to that Member State. For further details see section B.

Among the other significant increases in the species used in greater numbers, one should mention the increase in the use of ferrets ( $29 \%$ ), of cattle ( $36 \%$ ), of other birds $(25 \%)$ and of
amphibians ( $25 \%$ ). These increases, apart from ferrets, are all to be attributed to some of the new Member States.

The use of non-human primates remained as in previous reports at around $0,1 \%$ of the total number of animals used. However, by looking at the species, the number of prosimians used decreased by $38 \%$ while new world monkeys increased by $31 \%$.

Member States reported that these changes may be attributed to changes in regulatory requirements for pharmaceuticals and in toxicological safety testing.

As in 2002, no great apes were used for experimental or other scientific purposes in 2005.

## III.1.4. Comparison with the data of the previous reports for the EU 15

Since the total number of animals includes the data from the 10 new Member States it is not possible to draw a comparison per se with the results of the previous reports. However, to allow for some comparisons of trends of the animal use, separate Table 1 bis and 1 tris were drawn. Table 1 bis contains the data of EU 15 and Table 1 tris the data of EU 10 respectively.

In EU 15, the total number of animals used increased in 2005 by 339,279 which represents an increase of $3,1 \%$ with regard to 2002.

By examining the data by species, the major increase observed in 2005 is the additional use of about 579,000 mice ( $10,6 \%$ ). However this increase of mice is partly compensated by a decrease of the number of rats, hamsters and other rodents used ( $36 \%$ ). In 2005 there is also an increase of the number of rabbits used for experimental purposes $(9,5 \%)$.

Among the other classes of animals, the use of ferrets for carnivores ( $20,8 \%$ ) and the use of other mammals $(30 \%)$ has increased. The changes in the use of non-human primates as explained in chapter III.1.3 are mostly results of changes in EU 15 as only 57 old world monkeys were used in EU 10 in 2005.

On the other hand, the use of all species, within the class of artio and perissodactyla have decreased in comparison to 2002. The same is observed with birds. Finally, one can observe a substantial decrease of $73 \%$ in the use of reptiles.

Further breaking down the category 'other', Member States reported use of the following species:

Other rodents: gerbils, old world jerboas (Jaculus jaculus); chinchilla, beaver, ground squirrel, hamsters, aremenio (Cricetulus migratorius) and different species of mice;

Other carnivores: wild-life species used for zoological and ecological studies (e.g. foxes, badgers, seals), otters, fitchew;

Other mammals: boars, bats and shrews, llama, mole, European bison and red deer;
Other birds: mainly coturnix japonica and bob-white quail, poultry species, and zebra finches, canary, parakeet, parrot and farmed avian species for example, (Gallus gallus domesticus)

Table 1.1: Total number of animals used for experimental purposes in the EU Member States
Data of 2005 (*)

| Species | AT | BE | CY | CZ | DE | DK | EL | ES | EE | FR | HU | IE | IT | LV | LT | LU | MT | NL | PL | PT | FI | SI | SK | SE | UK | Totals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice | 128634 | 488125 | 967 | 82252 | 1084358 | 208375 | 15340 | 393217 | 4350 | 1510334 | 138312 | 17776 | 534614 | 10480 | 5116 | 3280 | 0 | 240048 | 126492 | 28318 | 120636 | 8556 | 14975 | 213727 | 1052064 | 6430346 |
| 2.b. Rats | 11920 | 106483 | 0 | 31703 | 435417 | 85664 | 6024 | 125754 | 484 | 424387 | 109479 | 7722 | 279774 | 2376 | 493 | 720 | 0 | 116608 | 51558 | 6793 | 28358 | 2732 | 6761 | 83321 | 411501 | 2336032 |
| 1.c. Guinea-Pigs | 3149 | 39530 | 0 | 4075 | 37761 | 5046 | 574 | 16780 | 0 | 79350 | 8360 | 4 | 11533 | 297 | 0 | 100 | 0 | 7479 | 10763 | 379 | 563 | 38 | 594 | 2014 | 28918 | 257307 |
| 1.d. Hamsters | 117 | 1874 | 0 | 220 | 7916 | 402 | 0 | 908 | 0 | 8691 | 137 | 0 | 1537 | 0 | 0 | 0 | 0 | 5322 | 243 | 129 | 126 | 0 | 0 | 167 | 3746 | 31535 |
| 1.e. Other Rodents | 107 | 2260 | 0 | 5798 | 7622 | 6381 | 40 | 294 | 0 | 12683 | 381 | 0 | 2303 | 0 | 0 | 0 | 0 | 3089 | 10826 | 0 | 3187 | 18 | 0 | 1269 | 8216 | 64474 |
| 1.f. Rabbits | 18439 | 21159 | 0 | 5567 | 103329 | 5805 | 1255 | 11878 | 66 | 93282 | 9152 | 379 | 9916 | 166 | 158 | 20 | 0 | 8251 | 3101 | 594 | 1214 | 533 | 782 | 2112 | 15523 | 312681 |
| 1.g. Cats | 12 | 81 | 0 | 29 | 1023 | 16 | 0 | 168 | 0 | 1313 | 124 | 119 | 30 | 0 | 0 | 0 | 0 | 334 | 121 | 0 | 0 | 0 | 0 | 220 | 308 | 3898 |
| 2.h. Dogs | 85 | 1295 | 0 | 264 | 4868 | 566 | 14 | 685 | 0 | 5539 | 1206 | 167 | 1064 | 0 | 0 | 0 | 0 | 1049 | 618 | 36 | 103 | 15 | 6 | 1166 | 5373 | 24119 |
| 1.i. Ferrets | 0 | 154 | 0 | 159 | 560 | 19 | 0 | 237 | 0 | 155 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 256 | 19 | 0 | 80 | 0 | 0 | 47 | 1004 | 2690 |
| 2.j. Other Carnivores | 0 | 0 | 0 | 7 | 235 | 242 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 151 | 6970 | 0 | 5 | 0 | 0 | 163 | 938 | 8711 |
| 1.k. Horses, donkeys and cross breds | 71 | 108 | 0 | 314 | 755 | 62 | 1 | 42 | 0 | 223 | 6 | 189 | 63 | 0 | 0 | 0 | 0 | 1705 | 681 | 8 | 125 | 1 | 0 | 650 | 308 | 5312 |
| 1.1. Pigs | 818 | 1876 | 0 | 1392 | 13166 | 7697 | 448 | 4818 | 0 | 6587 | 882 | 382 | 2579 | 0 | 0 | 0 | 0 | 9853 | 7358 | 113 | 1471 | 16 | 0 | 2722 | 4127 | 66305 |
| 1.m. Goats | 44 | 157 | 0 | 56 | 275 | 199 | 0 | 119 | 0 | 442 | 2 | 0 | 20 | 0 | 0 | 0 | 0 | 328 | 130 | 4 | 73 | 0 | 0 | 23 | 274 | 2146 |
| 1.n. Sheep | 195 | 445 | 0 | 720 | 3517 | 156 | 99 | 821 | 0 | 4992 | 381 | 601 | 584 | 0 | 0 | 0 | 0 | 2667 | 2023 | 290 | 445 | 57 | 0 | 256 | 11772 | 30021 |
| 1.o. Cattle | 536 | 944 | 0 | 711 | 2909 | 489 | 0 | 294 | 0 | 1296 | 32 | 2109 | 1174 | 0 | 0 | 0 | 0 | 4410 | 13834 | 45 | 455 | 0 | 0 | 727 | 6306 | 36271 |
| 1.p. Prosimians | 0 | 0 | 0 | 0 | 99 | 0 | 0 | 0 | 0 | 578 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 677 |
| 1.q. N W Monkeys | 0 | 0 | 0 | 0 | 408 | 0 | 0 | 1 | 0 | 433 | 0 | 0 | 17 | 0 | 0 | 0 | 0 | 50 | 0 | 0 | 0 | 0 | 0 | 12 | 643 | 1564 |
| 1.r. O W Monkeys | 56 | 449 | 0 | 51 | 1579 | 0 | 1 | 81 | 0 | 2778 | 6 | 0 | 395 | 0 | 0 | 0 | 0 | 277 | 0 | 0 | 0 | 0 | 0 | 63 | 2472 | 8202 |
| 1.s. Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals | 0 | 59 | 0 | 188 | 115 | 185 | 0 | 60 | 0 | 0 | 0 | 48 | 68 | 0 | 0 | 0 | 0 | 13 | 5061 | 1 | 972 | 0 | 0 | 639 | 2541 | 9950 |
| 1.u.Quail | 14 | 425 | 0 | 30 | 2457 | 0 | 0 | 1 | 0 | 4023 | 283 | 0 | 0 | 0 | 0 | 0 | 0 | 152 | 1470 | 0 | 0 | 0 | 251 | 0 | 140 | 9246 |
| 1.v. Other birds | 1011 | 13266 | 0 | 126211 | 39150 | 7784 | 21 | 8424 | 0 | 102240 | 17151 | 2024 | 31697 | 0 | 0 | 0 | 0 | 111081 | 61148 | 112 | 5773 | 22 | 0 | 7838 | 114860 | 649813 |
| 1.w. Reptiles | 40 | 144 | 0 | 1475 | 136 | 54 | 0 | 10 | 0 | 0 | 25 | 0 | 378 | 0 | 0 | 0 | 0 | 7 | 121 | 0 | 0 | 3 | 0 | 0 | 84 | 2477 |
| 1.x. Amphibians | 865 | 6177 | 0 | 293 | 10432 | 840 | 975 | 419 | 0 | 15675 | 1709 | 0 | 4636 | 0 | 0 | 0 | 0 | 3231 | 13216 | 51 | 20 | 0 | 0 | 5496 | 10585 | 74620 |
| 1.y. Fish | 1199 | 33965 | 0 | 69418 | 64337 | 35958 | 901300 | 30584 | 0 | 50397 | 9581 | 6420 | 14584 | 0 | 0 | 0 | 0 | 14838 | 43076 | 4748 | 93220 | 0 | 0 | 183049 | 192504 | 1749178 |
| 1.z. TOTAL | 167312 | 718976 | 967 | 330933 | 1822424 | 365940 | 926092 | 595597 | 4900 | 2325398 | 297209 | 37940 | 896966 | 13319 | 5767 | 4120 | 0 | 531199 | 358829 | 41621 | 256826 | 11991 | 23369 | 505681 | 1874207 | 12117583 |

(*) France reporting for 2004

Table 1.1 Bis: Total number of animals used for experimental purposes in the 15 EU Member States reporting before 2005

Data of 2005 (*)

| Species | AT | BE | DE | DK | EL | ES | FR | IE | IT | LU | NL | PT | FI | SE | UK | Totals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice | 128634 | 488125 | 1084358 | 208375 | 15340 | 393217 | 1510334 | 17776 | 534614 | 3280 | 240048 | 28318 | 120636 | 213727 | 1052064 | 6038846 |
| 1.b. Rats | 11920 | 106483 | 435417 | 85664 | 6024 | 125754 | 424387 | 7722 | 279774 | 720 | 116608 | 6793 | 28358 | 83321 | 411501 | 2130446 |
| 1.c. Guinea-Pigs | 3149 | 39530 | 37761 | 5046 | 574 | 16780 | 79350 | 4 | 11533 | 100 | 7479 | 379 | 563 | 2014 | 28918 | 233180 |
| 1.d. Hamsters | 117 | 1874 | 7916 | 402 | 0 | 908 | 8691 | 0 | 1537 | 0 | 5322 | 129 | 126 | 167 | 3746 | 30935 |
| 1.e. Other Rodents | 107 | 2260 | 7622 | 6381 | 40 | 294 | 12683 | 0 | 2303 | 0 | 3089 | 0 | 3187 | 1269 | 8216 | 47451 |
| 1.f. Rabbits | 18439 | 21159 | 103329 | 5805 | 1255 | 11878 | 93282 | 379 | 9916 | 20 | 8251 | 594 | 1214 | 2112 | 15523 | 293156 |
| 1.g. Cats | 12 | 81 | 1023 | 16 | 0 | 168 | 1313 | 119 | 30 | 0 | 334 | 0 | 0 | 220 | 308 | 3624 |
| 1.h. Dogs | 85 | 1295 | 4868 | 566 | 14 | 685 | 5539 | 167 | 1064 | 0 | 1049 | 36 | 103 | 1166 | 5373 | 22010 |
| 1.i. Ferrets | 0 | 154 | 560 | 19 | 0 | 237 | 155 | 0 | 0 | 0 | 256 | 0 | 80 | 47 | 1004 | 2512 |
| 1.j. Other Carnivores | 0 | 0 | 235 | 242 | 0 | 0 | 0 | 0 | 0 | 0 | 151 | 0 | 5 | 163 | 938 | 1734 |
| 1.k. Horses, donkeys and crossbreeds | 71 | 108 | 755 | 62 | 1 | 42 | 223 | 189 | 63 | 0 | 1705 | 8 | 125 | 650 | 308 | 4310 |
| 1.1. Pigs | 818 | 1876 | 13166 | 7697 | 448 | 4818 | 6587 | 382 | 2579 | 0 | 9853 | 113 | 1471 | 2722 | 4127 | 56657 |
| 1.m. Goats | 44 | 157 | 275 | 199 | 0 | 119 | 442 | 0 | 20 | 0 | 328 | 4 | 73 | 23 | 274 | 1958 |
| 1.n. Sheep | 195 | 445 | 3517 | 156 | 99 | 821 | 4992 | 601 | 584 | 0 | 2667 | 290 | 445 | 256 | 11772 | 26840 |
| 1.0. Cattle | 536 | 944 | 2909 | 489 | 0 | 294 | 1296 | 2109 | 1174 | 0 | 4410 | 45 | 455 | 727 | 6306 | 21694 |
| 1.p. Prosimians | 0 | 0 | 99 | 0 | 0 | 0 | 578 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 677 |
| 1.q. N W Monkeys | 0 | 0 | 408 | 0 | 0 | 1 | 433 | 0 | 17 | 0 | 50 | 0 | 0 | 12 | 643 | 1564 |
| 1.r. O W Monkeys | 56 | 449 | 1579 | 0 | 1 | 83 | 2778 | 0 | 395 | 0 | 277 | 0 | 0 | 63 | 2472 | 8153 |
| 1.s. Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals | 0 | 59 | 115 | 185 | 0 | 60 | 0 | 48 | 68 | 0 | 13 | 1 | 972 | 639 | 2541 | 4701 |
| 1.u. Quail | 14 | 425 | 2457 | 0 | 0 | 1 | 4023 | 0 | 0 | 0 | 152 | 0 | 0 | 0 | 140 | 7212 |
| 1.v. Other birds | 1011 | 13266 | 39150 | 7784 | 21 | 8424 | 102240 | 2024 | 31697 | 0 | 111081 | 112 | 5773 | 7838 | 114860 | 445281 |
| 1.w. Reptiles | 40 | 144 | 136 | 54 | 0 | 10 | 0 | 0 | 378 | 0 | 7 | 0 | 0 | 0 | 84 | 853 |
| 1.x. Amphibians | 865 | 6177 | 10432 | 840 | 975 | 419 | 15675 | 0 | 4636 | 0 | 3231 | 51 | 20 | 5496 | 10585 | 59402 |
| 1.y. Fish | 1199 | 33965 | 64337 | 35958 | 901300 | 30584 | 50397 | 6420 | 14584 | 0 | 14838 | 4748 | 93220 | 183049 | 192504 | 1627103 |
| 1.z. TOTAL | 167312 | 718976 | 1822424 | 365940 | 926092 | 595597 | 2325398 | 37940 | 896966 | 4120 | 531199 | 41621 | 256826 | 505681 | 1874207 | 11070299 |

(*) France reporting for 2004

Table 1.1 Tris: Total number of animals used for experimental purposes in the 10 New EU Member States
Reporting for 2005

| Species | CY | CZ | EE | HU | LV | LT | MT | PO | SI | SK | Totals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 967 | 82252 | 4350 | 138312 | 10480 | 5116 | 0 | 126492 | 8556 | 14975 | 391500 |
| 1.b. Rats (Rattus norvegicus) | 0 | 31703 | 484 | 109479 | 2376 | 493 | 0 | 51558 | 2732 | 6761 | 205586 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 0 | 4075 | 0 | 8360 | 297 | 0 | 0 | 10763 | 38 | 594 | 24127 |
| 1.d. Hamsters (Mesocricetus) | 0 | 220 | 0 | 137 | 0 | 0 | 0 | 243 | 0 | 0 | 600 |
| 1.e. Other Rodents (other Rode |  | 5798 | 0 | 381 | 0 | 0 | 0 | 10826 | 18 | 0 | 17023 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 0 | 5567 | 66 | 9152 | 166 | 158 | 0 | 3101 | 533 | 782 | 19525 |
| 1.g. Cats (Felis catus) | 0 | 29 | 0 | 124 | 0 | 0 | 0 | 121 | 0 | 0 | 274 |
| 1.h. Dogs (Canis familiaris) | 0 | 264 | 0 | 1206 | 0 | 0 | 0 | 618 | 15 | 6 | 2109 |
| 1.i. Ferrets (Mustela putorius furo) | 0 | 159 | 0 | 0 | 0 | 0 | 0 | 19 | 0 | 0 | 178 |
| 1.j. Other Carnivores (other Carnivores) | 0 | 7 | 0 | 0 | 0 | 0 | 0 | 6970 | 0 | 0 | 6977 |
| 1.k. Horses, donkeys and crossbred | 0 | 314 | 0 | 6 | 0 | 0 | 0 | 681 | 1 | 0 | 1002 |
| 1.I. Pigs (Sus) | 0 | 1392 | 0 | 882 | 0 | 0 | 0 | 7358 | 16 | 0 | 9648 |
| 1.m. Goats (Capra) | 0 | 56 | 0 | 2 | 0 | 0 | 0 | 130 | 0 | 0 | 188 |
| 1.n. Sheep (Ovis) | 0 | 720 | 0 | 381 | 0 | 0 | 0 | 2023 | 57 | 0 | 3181 |
| 1.0. Cattle (Bos) | 0 | 711 | 0 | 32 | 0 | 0 | 0 | 13834 | 0 | 0 | 14577 |
| 1.p. Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. New World Monkeys (Ceboidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 0 | 51 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 57 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 0 | 188 | 0 | 0 | 0 | 0 | 0 | 5061 | 0 | 0 | 5249 |
| 1.u. Quail (Coturnix coturnix) | 0 | 30 | 0 | 283 | 0 | 0 | 0 | 1470 | 0 | 251 | 2034 |
| 1.v. Other birds (other Aves) | 0 | 126211 | 0 | 17151 | 0 | 0 | 0 | 61148 | 22 | 0 | 204532 |
| 1.w. Reptiles (Reptilia) | 0 | 1475 | 0 | 25 | 0 | 0 | 0 | 121 | 3 | 0 | 1624 |
| 1.x. Amphibians (Amphibia) | 0 | 293 | 0 | 1709 | 0 | 0 | 0 | 13216 | 0 | 0 | 15218 |
| 1.y. Fish (Pisces) | 0 | 69418 | 0 | 9581 | 0 | 0 | 0 | 43076 | 0 | 0 | 122075 |
| 1.z. TOTAL | 967 | 330933 | 4900 | 297209 | 13319 | 5767 | 0 | 358829 | 11991 | 23369 | 1047284 |

Table 1.2: Classes of animals used for experimental purposes in the EU Member States
Data of 2005 (*)

| Species | AT | BE | CY | CZ | DE | DK | EL | ES | EE | FR | HU | IE | IT | LV | LT | LU | NL | PL | PT | FI | SI | SK | SE | UK | Totals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Mice | 128634 | 488125 | 967 | 82252 | 1084358 | 208375 | 15340 | 393217 | 4350 | 1510334 | 138312 | 17776 | 534614 | 10480 | 5116 | 3280 | 240048 | 126492 | 28318 | 120636 | 8556 | 14975 | 213727 | 1052064 | 6430346 |
| Rats | 11920 | 106483 | 0 | 31703 | 435417 | 85664 | 6024 | 125754 | 484 | 424387 | 109479 | 7722 | 279774 | 2376 | 493 | 720 | 116608 | 51558 | 6793 | 28358 | 2732 | 6761 | 83321 | 411501 | 2336032 |
| Guinea-Pigs | 3149 | 39530 | 0 | 4075 | 37761 | 5046 | 574 | 16780 | 0 | 79350 | 8360 | 4 | 11533 | 297 | 0 | 100 | 7479 | 10763 | 379 | 563 | 38 | 594 | 2014 | 28918 | 257307 |
| Golden hamsters + other rodents | 224 | 4134 | 0 | 6018 | 15538 | 6783 | 40 | 1202 | 0 | 21374 | 518 | 0 | 3840 | 0 | 0 | 0 | 8411 | 11069 | 129 | 3313 | 18 | 0 | 1436 | 11962 | 96009 |
| Rabbits | 18439 | 21159 | 0 | 5567 | 103329 | 5805 | 1255 | 11878 | 66 | 93282 | 9152 | 379 | 9916 | 166 | 158 | 20 | 8251 | 3101 | 594 | 1214 | 533 | 782 | 2112 | 15523 | 312681 |
| Cold-blooded animals(1) | 2104 | 40286 | 0 | 71186 | 74905 | 36852 | 902275 | 31013 | 0 | 66072 | 11315 | 6420 | 19598 | 0 | 0 | 0 | 18076 | 56413 | 4799 | 93240 | 3 | 0 | 188545 | 203173 | 1826275 |
| birds (2) | 1025 | 13691 | 0 | 126241 | 41607 | 7784 | 21 | 8425 | 0 | 106263 | 17434 | 2024 | 31697 | 0 | 0 | 0 | 111233 | 62618 | 112 | 5773 | 22 | 251 | 7838 | 115000 | 659059 |
| Artio+Perissodactyla (3) | 1664 | 3530 | 0 | 3193 | 20622 | 8603 | 548 | 0 | 0 | 13540 | 1303 | 3281 | 4420 | 0 | 0 | 0 | 18963 | 24026 | 460 | 2569 | 74 | 0 | 4378 | 22787 | 140055 |
| Carnivores (4) | 97 | 1530 | 0 | 459 | 6686 | 843 | 14 | 1090 | 0 | 7007 | 1330 | 286 | 1094 | 0 | 0 | 0 | 1790 | 7728 | 36 | 188 | 15 | 6 | 1596 | 7623 | 39418 |
| Prosimians+monkeys+ apes | 56 | 449 | 0 | 51 | 2086 | 0 | 1 | 84 | 0 | 3789 | 6 | 0 | 412 | 0 | 0 | 0 | 327 | 0 | 0 | 0 | 0 | 0 | 75 | 3115 | 10451 |
| Other Mammals | 0 | 59 | 0 | 188 | 115 | 185 | 0 | 60 | 0 | 0 | 0 | 48 | 68 | 0 | 0 | 0 | 13 | 5061 | 1 | 972 | 0 | 0 | 639 | 2541 | 9950 |
| Total | 167312 | 718976 | 967 | 330933 | 1822424 | 365940 | 926094 | 595597 | 4900 | 2325398 | 297209 | 37940 | 896966 | 13319 | 5767 | 4120 | 531199 | 358829 | 41621 | 256826 | 11991 | 23369 | 505681 | 1874207 | 12117583 |


| Species\% total | AT | BE | CY | CZ | DE | DK | EL | ES | EE | FR | HU | IE | IT | LV | LT | LU | NL | PL | PT | FI | SI | SK | SE | UK | Mean |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Mice | 76,88 | 67,89 | 100 | 24,85 | 59,50 | 56,94 | 1,66 | 66,02 | 88,78 | 64,95 | 46,54 | 46,85 | 59,60 | 78,68 | 88,71 | 79,61 | 45,19 | 35,25 | 68,04 | 46,97 | 71,35 | 64,08 | 42,27 | 56,13 | 53,07 |
| Rats | 7,12 | 14,81 | 0,00 | 9,58 | 23,89 | 23,41 | 0,65 | 21,11 | 9,88 | 18,25 | 36,84 | 20,35 | 31,19 | 17,84 | 8,55 | 17,48 | 21,95 | 14,37 | 16,32 | 11,04 | 22,78 | 28,93 | 16,48 | 21,96 | 19,28 |
| Guinea-Pigs | 1,88 | 5,50 | 0,00 | 1,23 | 2,07 | 1,38 | 0,06 | 2,82 | 0,00 | 3,41 | 2,81 | 0,01 | 1,29 | 2,23 | 0,00 | 2,43 | 1,41 | 3,00 | 0,91 | 0,22 | 0,32 | 2,54 | 0,40 | 1,54 | 2,12 |
| Golden hamsters + other rodents | 0,13 | 0,57 | 0,00 | 1,82 | 0,85 | 1,85 | 0,00 | 0,20 | 0,00 | 0,92 | 0,17 | 0,00 | 0,43 | 0,00 | 0,00 | 0,00 | 1,58 | 3,08 | 0,31 | 1,29 | 0,15 | 0,00 | 0,28 | 0,64 | 0,79 |
| Rabbits | 11,02 | 2,94 | 0,00 | 1,68 | 5,67 | 1,59 | 0,14 | 1,99 | 1,35 | 4,01 | 3,08 | 1,00 | 1,11 | 1,25 | 2,74 | 0,49 | 1,55 | 0,86 | 1,43 | 0,47 | 4,45 | 3,35 | 0,42 | 0,83 | 2,58 |
| Cold-blooded animals(1) | 1,26 | 5,60 | 0,00 | 21,51 | 4,11 | 10,07 | 97,43 | 5,21 | 0,00 | 2,84 | 3,81 | 16,92 | 2,18 | 0,00 | 0,00 | 0,00 | 3,40 | 15,72 | 11,53 | 36,30 | 0,03 | 0,00 | 37,29 | 10,84 | 15,07 |
| birds (2) | 0,61 | 1,90 | 0,00 | 38,15 | 2,28 | 2,13 | 0,00 | 1,41 | 0,00 | 4,57 | 5,87 | 5,33 | 3,53 | 0,00 | 0,00 | 0,00 | 20,94 | 17,45 | 0,27 | 2,25 | 0,18 | 1,07 | 1,55 | 6,14 | 5,44 |
| Artio+Perissodactyla (3) | 0,99 | 0,49 | 0,00 | 0,96 | 1,13 | 2,35 | 0,06 | 1,02 | 0,00 | 0,58 | 0,44 | 8,65 | 0,49 | 0,00 | 0,00 | 0,00 | 3,57 | 6,70 | 1,11 | 1,00 | 0,62 | 0,00 | 0,87 | 1,22 | 1,16 |
| Carnivores (4) | 0,06 | 0,21 | 0,00 | 0,14 | 0,37 | 0,23 | 0,00 | 0,18 | 0,00 | 0,30 | 0,45 | 0,75 | 0,12 | 0,00 | 0,00 | 0,00 | 0,34 | 2,15 | 0,09 | 0,07 | 0,13 | 0,03 | 0,32 | 0,41 | 0,33 |
| Prosimians+monkeys+ apes | 0,03 | 0,06 | 0,00 | 0,02 | 0,11 | 0,00 | 0,00 | 0,01 | 0,00 | 0,16 | 0,00 | 0,00 | 0,05 | 0,00 | 0,00 | 0,00 | 0,06 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,01 | 0,17 | 0,09 |
| Other Mammals | 0,00 | 0,01 | 0,00 | 0,06 | 0,01 | 0,05 | 0,00 | 0,01 | 0,00 | 0,00 | 0,00 | 0,13 | 0,01 | 0,00 | 0,00 | 0,00 | 0,00 | 1,41 | 0,00 | 0,38 | 0,00 | 0,00 | 0,13 | 0,14 | 0,08 |
| Total | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |

Malta has reported 0 animals used in 2005
(*) France reporting for 2004
(1) $\quad=$ Reptiles + amphibians + fish
(2) $=$ Quails and other birds
(3)
(3) $\quad=$ Horses, donkeys and cross bred + pigs + goats and sheep + cattle
(4) $=$ cats + dogs + ferrets + other carnivores

## III.2. Results of EU Table 1: $\underline{\text { Origin of animals used }}$

## III.2.1. The data on the origin of the species

The consolidated results of EU Table 1 on the origin of some selected species used for experimental purposes in the 25 Member States are reported in Table 1.3 at the end of this chapter. The consolidated table only indicates species for which the origin must be reported.

In addition, EU Table 1 requires that Member States report the number of animals re-used in experiments.

## III.2.2. Treatment and interpretation of the data

The data of column 1.3 and 1.4 of Table 1.3 of this report have been grouped to represent animals coming from the Community.

Figure 1.2 represents the percentage of origin of animals versus the species.

Figure 1.2: Origin of species


The chart shows that the majority of the species originated from the EU countries. However, certain species such as cats, dogs and ferrets and old world monkeys are of nonEuropean origin.

## III.2.3. Comparison with data of the previous report

The general pattern on the origin of the species is quite similar to that observed in the previous reports. It should be noted however, that for the first time in 2005 the prosimians
were all of EU origin. A similar trend can also be observed with the new world monkeys where an increasing amount was either of EU or ETS 123 origin at the expense of other countries. Also, old world monkeys coming from EU origins increased. On the other hand the number of cats not of European origin has increased in comparison to the report of 2002.

Table 1.3: Number of animals used in relation to their place of origin
Data of 2005

| 1.1.Species | 1.2. Total | 1.3.Animals coming from registered breeding or supplying establishments within the reporting country | 1.4. Animals coming from elsewhere in the EC | 1.5.Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6.Animals coming from other origins | 1.7.Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 6430346 | 5408519 | 842034 | 38621 | 141172 | 254 |
| 1.b. Rats (Rattus norvegicus) | 2336032 | 2002798 | 294875 | 17328 | 21031 | 118 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 257307 | 178363 | 69291 | 3245 | 6408 | 2 |
| 1.d. Hamsters (Mesocricetus) | 31535 | 25276 | 4448 | 641 | 1170 | 0 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 312681 | 294616 | 15595 | 839 | 1631 | 13488 |
| 1.g. Cats (Felis catus) | 3898 | 2251 | 492 | 34 | 1121 | 1007 |
| 1.h. Dogs (Canis familiaris) | 24119 | 15542 | 2732 | 220 | 5625 | 3763 |
| 1.i. Ferrets (Mustela putorius furo) | 2690 | 1662 | 240 | 50 | 738 | 22 |
| 1.p. Prosimians (Prosimia) | 677 | 578 | 99 | 0 | 0 | 111 |
| 1.q. New World Monkeys (Ceboidea) | 1564 | 1244 | 195 | 65 | 60 | 410 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 8210 | 1459 | 719 | 38 | 5994 | 1740 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.u. Quail (Coturnix coturnix) | 9246 | 8860 | 0 | 152 | 234 | 0 |
| 1.z. TOTAL | 9418305 | 7941168 | 1230720 | 61233 | 185184 |  |

Note 1
(Note 2:
Note 3:

Column 1.5 concerns only those Member countries of the Council of Europe which, at the beginning of the reporting period, are Parties to the Convention ETS 123. Thus an updated list of those countries has to be used when filling in this column
Only species for which origin has to be reported are included in this table)
The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2.

## III.3. Results of EU Table 2: $\underline{\text { Purposes of the experiments }}$

## III.3.1. The data on purpose of the experiments

The consolidated data on purposes of the experiments of the 25 Member States are presented in Table 2.1 at the end of this chapter.

## III.3.2. Treatment and interpretation of the data

Table 2.2 presents the results of the consolidated data of the purposes of the procedures carried out in the 25 Member States in 2005. In order to facilitate the presentation of results some species and some purposes were grouped.

The percentage of the number of animals used for selected purposes is presented in Figure 2.1.

Figure 2.1
Purposes of experiments


As in previous years, more than $60 \%$ of animals were used in research and development for human medicine, veterinary medicine, dentistry and in fundamental biology studies.

Production and quality control of products and devices in human medicine, veterinary medicine and dentistry required the use of $15,3 \%$ of the total number of animals reported in 2005.

Toxicological and other safety evaluation represents $8 \%$ of the total number of animals used for experimental purposes.

## III.3.3. Comparison with the data of the previous report

It must be remembered that the comparison is aiming to detect changes in trends rather than drawing formal conclusions. The most significant change that can be identified is the number of animals used for toxicological and other safety evaluation, which has dropped from about $9,9 \%$
(data of 2002) to $8 \%$ for the data submitted by 25 Member States for this report. The decrease is also important in total numbers, i.e. from $1,066,047$ to $1,026,286$ animals while at the same time covering the 10 new Member States.

The percentage of animals used for education and training is also showing a decreasing trend while other purposes seem to indicate an increase. In terms of numbers of animals the decrease ranges from 341,967 to 198,994 and the increase from 597,960 to 984,238 respectively.

The decrease of animals used for education and training can be attributed to both an uptake of alternative techniques and the re-use of animals.
'Other' purposes covers amongst other things virology, immunology for production of monoclonal and polyclonal antibodies, physiology of foetal-maternal interaction in mouse gene transgensis, oncological treatment, pharmaceutical R\&D, combined drug testing and genetics.

Table 2.2: Number of animals used for selected purposes versus species

| Species | Biological studies of a fundament al nature | Research, developm ent and quality control of products and devices for human medicine and dentistry and for veterinary medicine) | Toxicologic al and other safety evaluations (including safety evaluation of products) | Diagnosi $s$ of disease | Education and training | Other | Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Mice | 2465474 | 2727254 | 384741 | 225524 | 86597 | 551356 | 6440946 |
| Rats | 677533 | 1161517 | 350275 | 13564 | 50048 | 72876 | 2325813 |
| Other rodents | 53241 | 230403 | 56006 | 4512 | 2606 | 6548 | 353316 |
| Rabbits | 15463 | 237411 | 38761 | 8322 | 3856 | 8829 | 312642 |
| Carnivores | 11605 | 9309 | 14884 | 348 | 674 | 2339 | 39159 |
| Artio+perissodactyla | 64419 | 41079 | 4542 | 4100 | 9491 | 16341 | 139972 |
| Prosimians+monkeys+apes | 1456 | 1397 | 7004 | 16 | 42 | 536 | 10451 |
| Other mammals | 8978 | 214 | 15 | 0 | 4 | 739 | 9950 |
| Birds | 251443 | 249024 | 53935 | 9723 | 5440 | 89494 | 659059 |
| Cold-blooded animals | 485858 | 942973 | 116123 | 5905 | 40236 | 235180 | 1826275 |
| TOTAL | 4035470 | 5600581 | 1026286 | 272014 | 198994 | 984238 | 12117583 |

Figure 2.2 presents the number of animals used for selected purposes by classes of species.
From Figure 2.2 one can see that the highest amount of use of mice and rats is attributed to fundamental biology and also of research, development and control of products and devices for medicine, dentistry and veterinary medicine. The use of cold-blooded animals is following a similar pattern for different purposes.

Figure 2.2
Species and experimental purposes


Table 2.1: Number of animals used in experiments for selected purposes Purposes versus species
data of 2005*

| 2.1Species | 2.2. <br> Biological studies of a fundamenta I nature | 2.3. Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding <br> toxicological and other safety evaluations counted in column 2.6) | 2.4.Production and quality control of products and devices for human medicine and dentistry | 2.5.Production and quality control of products and devices for veterinary medicine | 2.6.Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine | 2.7.Diagno sis of disease | 2.8.Education and training | 2.9.Other | 2.10.Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 2465474 | 1639698 | 902318 | 185238 | 384741 | 225524 | 86597 | 551356 | 6440946 |
| 1.b. Rats (Rattus norvegicus) | 677533 | 920875 | 209791 | 30851 | 350275 | 13564 | 50048 | 72876 | 2325813 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 12911 | 47490 | 111505 | 24323 | 53498 | 2150 | 1691 | 3739 | 257307 |
| 1.d. Hamsters (Mesocricetus) | 10716 | 6167 | 274 | 10098 | 1670 | 1395 | 390 | 825 | 31535 |
| 1.e. Other Rodents (other Rodentia) | 29614 | 30359 | 0 | 187 | 838 | 967 | 525 | 1984 | 64474 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 15463 | 32814 | 185572 | 19025 | 38761 | 8322 | 3856 | 8829 | 312642 |
| 1.g. Cats (Felis catus) | 1123 | 1044 | 138 | 687 | 222 | 64 | 129 | 491 | 3898 |
| 1.h. Dogs (Canis familiaris) | 1997 | 4457 | 244 | 1182 | 14621 | 243 | 500 | 616 | 23860 |
| 1.i. Ferrets (Mustela putorius furo) | 510 | 1299 | 42 | 14 | 41 | 41 | 45 | 698 | 2690 |
| 1.j. Other Carnivores (other Carnivore) | 7975 | 0 | 0 | 202 | 0 | 0 | 0 | 534 | 8711 |
| 1.k. Horses, donkeys and cross breds (Equidae) | 1293 | 472 | 203 | 1957 | 40 | 182 | 973 | 192 | 5312 |
| 1.I. Pigs (Sus) | 27052 | 15159 | 489 | 6610 | 3349 | 1888 | 5854 | 5821 | 66222 |
| 1.m. Goats (Capra) | 828 | 280 | 84 | 41 | 39 | 214 | 317 | 343 | 2146 |
| 1.n. Sheep (Ovis) | 10442 | 2721 | 5731 | 1217 | 457 | 871 | 956 | 7626 | 30021 |
| 1.o. Cattle (Bos) | 24804 | 3691 | 55 | 2369 | 657 | 945 | 1391 | 2359 | 36271 |
| 1.p. Prosimians (Prosimia) | 384 | 0 | 0 | 0 | 97 | 0 | 0 | 196 | 677 |
| 1.q. New World Monkeys (Ceboidea) | 357 | 327 | 43 | 0 | 650 | 16 | 5 | 166 | 1564 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 715 | 654 | 373 | 0 | 6257 | 0 | 37 | 174 | 8210 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 8978 | 144 | 0 | 70 | 15 | 0 | 4 | 739 | 9950 |
| 1.u. Quail (Coturnix coturnix) | 1722 | 0 | 0 | 0 | 3191 | 0 | 169 | 3913 | 8995 |
| 1.v. Other birds (other Aves) | 249721 | 104833 | 12727 | 131464 | 50744 | 9723 | 5271 | 85581 | 650064 |
| 1.w. Reptiles (Reptilia) | 1646 | 13 | 0 | 0 | 12 | 0 | 774 | 32 | 2477 |
| 1.x. Amphibians (Amphibia) | 55349 | 253 | 0 | 0 | 542 | 99 | 15666 | 2711 | 74620 |
| 1.y. Fish (Pisces) | 428863 | 933278 | 280 | 9149 | 115569 | 5806 | 23796 | 232437 | 1749178 |
| 1.z. TOTAL | 4035470 | 3746028 | 1429869 | 424684 | 1026286 | 272014 | 198994 | 984238 | 12117583 |

(*)France reporting for 2004

## III.4. Results of EU Table 3: Toxicological and safety evaluation by type of product/endpoints

## III.4.1. The data on toxicological and safety evaluation by type of products/endpoints

The consolidated table giving the number of animals used in toxicological and other safety evaluation of products (EU Table 3) in 25 Member States is presented in Table 3.1 at the end of this chapter.

The percentage of the number of animals used for different types of product is presented in Figure 3.1.

## III.4.2. Treatment and interpretation of the data

Figure 3.1
Animals used in toxicological and other safety experiments


In table 3.1 the number of animals used for toxicological or other safety evaluation is broken down into type of products for which testing was required.

Only $8 \%$ of the total number of animals used for experimental purposes is used for toxicological and other safety evaluation. This accounts for 1,026,286 animals (see III.3.3)

The percentage of animals used for toxicological evaluation of 4 groups of products/substances, i.e., animal feed, additives for human food consumption, cosmetics and household, is very small $(4,3 \%)$ when compared to the other products groups.

Products or devices used for human medicine, veterinary medicine and dentistry represents $50,9 \%$ of the animal used for toxicological or other safety evaluations.

The group of products/substances falling under the scrutiny of authorities concerned with safety of health and of the environment by chemical products, such as industrial chemicals and pesticides, used $19 \%$ of the animals for toxicological and other safety evaluations.

There is a strong decrease in the number of animals used for toxicological tests for products intended for industry, for agriculture, products for potential contaminants of the environment (decrease ranging from above 123,000 to below 98,000 ) and also tests for products for household and for additives in food for human consumption, categories using lower numbers, in comparison to the data submitted in the last statistical report.

There is a noticeable increase ( $50 \%$ ) in the number of animals used for testing cosmetics or toiletries, however, the actual numbers of animals in this category remain low (5,571 in total). This increase, attributed mainly to one old Member State, is worth noting in light of the legal requirement to phase out animal testing for cosmetics in the EU. There is also a significant increase in the number of animals used for tests for additives in food for animal consumption ( 3,447 to $34,225-10$ fold).

It should also be noted that in comparison to the 2002 report there is a significant increase in the number of animals used for other toxicological or safety evaluation (ranging from around 110,000 to 180,000 ). This category could benefit from further analysis. Member States reported that it concerned new methods and tests, such as: tests on transmission of microcystins on embryonic membrane; bioassays; toxicity evaluation for humans via the environment; and control of safety for toys.

Table 3.1: Number of animals used in toxicological and other safety evaluation Products versus species

Data of 2005*

| 3.1.Species | 3.2. Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3. <br> Products/ substances used or intended to be used mainly in agriculture | 3.4.Products/ <br> substances used or intended to be used mainly in industry | 3.5.Products/ <br> substances used or intended to be used mainly in the household | 3.6.Products/ <br> substances used or intended to be used mainly as cosmetics or toiletries | 3.7.Products/ <br> substances used or intended to be used mainly as additives in food for human consumption | 3.8.Products/ <br> substances used or intended to be used mainly as additives in food for animal consumption | 3.9.Potentialor actual contaminants in the general environment which do not appear in other columns | 3.10.Othertoxicological or safety evaluations | 3.11.Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 210840 | 18546 | 26677 | 72 | 1797 | 1268 | 1630 | 9264 | 116850 | 386944 |
| 1.b. Rats (Rattus norvegicus) | 210719 | 41903 | 44768 | 294 | 2226 | 2644 | 704 | 8883 | 36707 | 348648 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 35123 | 3051 | 7128 | 177 | 940 | 46 | 0 | 156 | 6877 | 53498 |
| 1.d. Hamsters (Mesocricetus ) | 1065 | 571 | 18 | 0 | 0 | 0 | 0 | 0 | 16 | 1670 |
| 1.e. Other Rodents (other Rodentia) | 300 | 68 | 28 | 0 | 0 | 0 | 0 | 442 | 0 | 838 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 26030 | 3593 | 4433 | 116 | 608 | 141 | 113 | 25 | 4094 | 39153 |
| 1.g. Cats (Felis catus) | 222 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 222 |
| 1.h. Dogs (Canis familiaris) | 12671 | 509 | 278 | 0 | 0 | 0 | 0 | 29 | 1118 | 14605 |
| 1.i. Ferrets (Mustela putorius furo) | 41 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 41 |
| 1.j. Other Carnivores (other Carnivore) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.k. Horses, donkeys and cross breds (Equidae) | 35 | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 40 |
| 1.I. Pigs (Sus) | 2246 | 90 | 47 | 0 | 0 | 76 | 444 | 103 | 241 | 3247 |
| 1.m. Goats (Capra) | 24 | 5 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 39 |
| 1.n. Sheep (Ovis) | 351 | 10 | 0 | 0 | 0 | 0 | 10 | 72 | 14 | 457 |
| 1.o. Cattle (Bos) | 489 | 48 | 0 | 0 | 0 | 0 | 105 | 0 | 15 | 657 |
| 1.p. Prosimians (Prosimia) | 97 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 97 |
| 1.q. New World Monkeys (Ceboidea) | 613 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 37 | 650 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 5057 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 1194 | 6257 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 15 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 15 |
| 1.u. Quail (Coturnix coturnix) | 0 | 3161 | 0 | 0 | 0 | 0 | 0 | 25 | 0 | 3186 |
| 1.v. Other birds (other Aves) | 9246 | 3728 | 98 | 0 | 0 | 0 | 31119 | 1437 | 5116 | 50744 |
| 1.w. Reptiles (Reptilia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 12 | 12 |
| 1.x. Amphibians (Amphibia) | 0 | 400 | 0 | 0 | 0 | 0 | 100 | 0 | 42 | 542 |
| 1.y. Fish (Pisces) | 6937 | 21944 | 12998 | 560 | 0 | 0 | 0 | 64286 | 7799 | 114524 |
| 1.z. TOTAL | 522121 | 97632 | 96479 | 1219 | 5571 | 4175 | 34225 | 84732 | 180132 | 1026286 |

(*) France reporting for 2004

## III.5. Results of EU Table 4: $\underline{\text { Animals used for studies of diseases }}$

## III.5.1. The data on animals used for studies of diseases

The consolidated table of results on animals used for studies of diseases (EU Table 4) in the 25 Member States is presented in Table 4.1 at the end of this chapter.

## III.5.2. Treatment and interpretation of the data

Table 4.1 gives the number of animals used per type of studies on diseases. In 2005, the number of animals used for the study of both animal and human diseases represented more than half $(57,5 \%)$ the total number of animals used for experimental purposes in the EU.

Figure 4.1 presents the percentage of animals used in studies per type of diseases.
The percentage of the number of animals used for studies of human diseases represents $81 \%$ of the total number of animals used for all studies of diseases.

Figure 4.1
Proportion of animals used for the study of diseases


In 2005, the proportion and the number of animals used (ranging from 900,000 to $1,329,000$ ) for the studies of animal diseases have increased significantly when compared with the report of 2002 .

It should be remembered that the studies on specific animal diseases are important in the light of epidemics of farm animals such as in the case of cows, foot and mouth disease, swine fever and more recently avian flew. Animals used also covers studies on genetic diseases.

An important part, around $60 \%$, of the increase of the total use of mice $(579,000)$ in comparison with 2002, can be attributed to different studies of diseases.

Table 4.1: Number of animals used in experiments for studies on human and animal diseases Main category of diseases versus species

Data of 2005 *

| 4.1 Species | 4.2 Human cardiovascular diseases | 4.3 Human nervous and mental disorders | 4.4 Human cancer (excluding evaluations of carcinogenic hazards or risks) | 4.5 Other human diseases | 4.6 Studies specific to animal diseases | 4.7 Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 233054 | 843362 | 801787 | 1862317 | 158718 | 3899238 |
| 1.b. Rats (Rattus norvegicus) | 154838 | 610191 | 80825 | 642300 | 5251 | 1493405 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 4721 | 7581 | 781 | 57019 | 5200 | 75302 |
| 1.d. Hamsters (Mesocricetus) | 2121 | 4471 | 579 | 7302 | 2931 | 17404 |
| 1.e. Other Rodents (other Rodentia) | 84 | 24311 | 487 | 12750 | 3038 | 40670 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 11601 | 3769 | 631 | 23941 | 7864 | 47806 |
| 1.g. Cats (Felis catus) | 13 | 203 | 52 | 339 | 992 | 1599 |
| 1.h. Dogs (Canis familiaris) | 1538 | 367 | 347 | 6001 | 2395 | 10648 |
| 1.i. Ferrets (Mustela putorius furo) | 228 | 159 | 33 | 1693 | 71 | 2184 |
| 1.j. Other Carnivores (other Carnivore) | 2 | 0 | 0 | 500 | 540 | 1042 |
| 1.k. Horses, donkeys and cross breds (Equidae) | 8 | 29 | 8 | 110 | 919 | 1074 |
| 1.1. Pigs (Sus) | 4902 | 943 | 198 | 8548 | 11226 | 25817 |
| 1.m. Goats (Capra) | 184 | 25 | 3 | 481 | 205 | 898 |
| 1.n. Sheep (Ovis) | 759 | 523 | 52 | 7138 | 7953 | 16425 |
| 1.0. Cattle (Bos) | 140 | 1841 | 0 | 2608 | 7727 | 12316 |
| 1.p. Prosimians (Prosimia) | 0 | 383 | 0 | 0 | 0 | 383 |
| 1.q. New World Monkeys (Ceboidea) | 58 | 204 | 2 | 810 | 0 | 1074 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 53 | 167 | 179 | 2882 | 9 | 3290 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 250 | 189 | 3 | 1777 | 65 | 2284 |
| 1.u. Quail (Coturnix coturnix) | 0 | 197 | 0 | 25 | 0 | 222 |
| 1.v. Other birds (other Aves) | 1443 | 6282 | 0 | 27269 | 159253 | 194247 |
| 1.w. Reptiles (Reptilia) | 13 | 115 | 0 | 24 | 79 | 231 |
| 1.x. Amphibians (Amphibia) | 1067 | 1338 | 2923 | 10297 | 277 | 15902 |
| 1.y. Fish (Pisces) | 300 | 3898 | 421 | 146936 | 954534 | 1106089 |
| 1.z. TOTAL | 417377 | 1510548 | 889311 | 2823067 | 1329247 | 6969550 |

(*) France reporting for 2004

Table 4.2: Number of animals used in studies of diseases by classes of animals

| Classes of animals | Human Cardiovascular diseases | Human nervous and mental disorder | Human cancer (excl. evaluation of carcino hazards) | Other human diseases | Specific animal diseases | Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Mice | 233054 | 843362 | 801787 | 1862317 | 158718 | 3899238 |
| Rats | 154838 | 610191 | 80825 | 642300 | 5251 | 1493405 |
| Guinea-Pigs | 4721 | 7581 | 781 | 57019 | 5200 | 75302 |
| Other rodents | 2205 | 28782 | 1066 | 20052 | 5969 | 58074 |
| Rabbits | 11601 | 3769 | 631 | 23941 | 7864 | 47806 |
| Carnivores | 1781 | 729 | 432 | 8533 | 3998 | 15473 |
| Artio + Perrisodactyla | 5993 | 3361 | 261 | 18885 | 28030 | 56530 |
| Prosimians+Monkeys+Apes | 111 | 754 | 181 | 3692 | 9 | 4747 |
| Other Mammals | 250 | 189 | 3 | 1777 | 65 | 2284 |
| Birds | 1443 | 6479 | 0 | 27294 | 159253 | 194469 |
| Cold-blooded animals | 1380 | 5351 | 3344 | 157257 | 954890 | 1122222 |
| TOTAL | 417377 | 1510548 | 889311 | 2823067 | 1329247 | 6969550 |


| Classes of animals\% | Human Cardiovascular diseases | Human nervous and mental disorder | Human cancer (excl. evaluation of carcino hazards) | Other human diseases | Specific animal diseases | Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Mice | 5,98 | 21,63 | 20,56 | 47,76 | 4,07 | 100,00 |
| Rats | 10,37 | 40,86 | 5,41 | 43,01 | 0,35 | 100,00 |
| Guinea-Pigs | 6,27 | 10,07 | 1,04 | 75,72 | 6,91 | 100,00 |
| Other rodents | 3,80 | 49,56 | 1,84 | 34,53 | 10,28 | 100,00 |
| Rabbits | 24,27 | 7,88 | 1,32 | 50,08 | 16,45 | 100,00 |
| Carnivores | 11,51 | 4,71 | 2,79 | 55,15 | 25,84 | 100,00 |
| Artio + Perrisodactyla | 10,60 | 5,95 | 0,46 | 33,41 | 49,58 | 100,00 |
| Prosimians+Monkeys+Apes | 2,34 | 15,88 | 3,81 | 77,78 | 0,19 | 100,00 |
| Other Mammals | 10,95 | 8,27 | 0,13 | 77,80 | 2,85 | 100,00 |
| Birds | 0,74 | 3,33 | 0,00 | 14,04 | 81,89 | 100,00 |
| Cold-blooded animals | 0,12 | 0,48 | 0,30 | 14,01 | 85,09 | 100,00 |
| TOTAL | 5,99 | 21,67 | 12,76 | 40,51 | 19,07 | 100,00 |

Species of Table 4.1 were grouped into classes of animals to present Table 4.2. The relative percentage of animals per classes of species used in studies by type of diseases has been calculated and is also presented in the lower part of Table 4.2.

Figure 4.2 presents the proportion of animals used by classes per type of studies of diseases.

Figure 4.2
Proportion of animals used by classes per type of studies of diseases


[^2]The top of each bar shows the relative percentage of animals used for studies on specific animal diseases. Two groups of animals i.e. birds and cold-blooded animals account for more than $80 \%$ of such studies. Member States reported that it is still current practice to test vaccines on these types of species. However, in some Member States only birds are used if the infection concerns bird species.

In 2005, the proportion of other mammals used for specific animal diseases has decreased but increased proportionally in studies of other human diseases.

Overall the general pattern of the proportion of animals used for the studies of diseases presented very little change when compared to the previous statistical report.

## III.6. Results of EU Table 5: Animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine

III.6.1. The data on animals used in production and quality control of products for human medicine and dentistry and for veterinary medicine

The consolidated table for the 25 Member States reporting the origin of the regulatory requirements in relation to animals used for the production and quality control of products for human medicine and dentistry and for veterinary medicine (EU Table 5) is presented in Table 5.1 of this report.

## III.6.2. Treatment and interpretation of the data

The number of animals used in tests for the production and quality control of products for human medicine and dentistry and for veterinary medicine represents $15,3 \%$ of the total number of animals used for experimental purposes. Figure 5.1 gives the percentages of the animals used for different regulatory purposes in this area.

Figure 5.1
Percentages of animals used for regulatory requirements for the production and quality control of products and devices for human medicine, dentistry and for veterinary medicine


The largest proportion of animals in this area (57\%) was used to simultaneously satisfy requirements from several legislations such as national, Community, Council of Europe or others. The testing carried out to satisfy the EU legislation including the European Pharmacopoeia covered $33,3 \%$ of the animals used in this area.

The increase of the percentage, from $43,1 \%$ to $56,8 \%$, of the number of animals used to satisfy simultaneously several pieces of legislation in comparison to 2002, is clearly showing an encouraging trend. This is likely to reflect a positive increase in harmonisation of different legislative requirements.

Another positive trend is the reduction of the number of animals, from 352,000 to 95,739 , used for "no regulatory requirements".

Table 5.1: Number of animals used in the production and quality control of products and devices for human medicine and dentistry and for veterinary medicine

Regulatory requirements versus species

| 5.1. Species | 5.2. National legislation specific to a single EC Member State1 | 5.3. EC legislation including European <br> Pharmacopoeia (requirements) | 5.4. Member Country of Council of Europe (but not EC) legislation2) | 5.5. Other legislation | 5.6. Any combination of $\begin{gathered} 5.2 / 5.3 / 5.4 / \\ 5.5 \end{gathered}$ | 5.7. No regulatory requirements | 5.8. Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 24912 | 326864 | 20 | 13463 | 685435 | 36912 | 1087606 |
| 1.b. Rats (Rattus norvegicus) | 5551 | 82479 | 0 | 18436 | 127504 | 6822 | 240792 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 8558 | 44713 | 7 | 6041 | 73163 | 3346 | 135828 |
| 1.d. Hamsters (Mesocricetus ) | 0 | 4528 | 0 | 0 | 5449 | 395 | 10372 |
| 1.e. Other Rodents (other Rodentia) | 0 | 0 | 0 | 0 | 187 | 0 | 187 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 2566 | 85556 | 0 | 308 | 87867 | 28300 | 204597 |
| 1.g. Cats (Felis catus) | 76 | 607 | 0 | 13 | 111 | 18 | 825 |
| 1.h. Dogs (Canis familiaris) | 21 | 1016 | 0 | 0 | 241 | 148 | 1426 |
| 1.i. Ferrets (Mustela putorius furo) | 14 | 30 | 0 | 0 | 6 | 6 | 56 |
| 1.j. Other Carnivores (other Carnivore) | 0 | 202 | 0 | 0 | 0 | 0 | 202 |
| 1.k. Horses, donkeys and cross breds (Equidae) | 229 | 219 | 0 | 2 | 281 | 1429 | 2160 |
| 1.I. Pigs (Sus) | 136 | 4363 | 0 | 9 | 1572 | 1019 | 7099 |
| 1.m. Goats (Capra) | 0 | 4 | 0 | 0 | 118 | 3 | 125 |
| 1.n. Sheep (Ovis) | 176 | 838 | 0 | 0 | 3650 | 2284 | 6948 |
| 1.o. Cattle (Bos) | 125 | 1462 | 26 | 10 | 533 | 268 | 2424 |
| 1.p. Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. New World Monkeys (Ceboidea) | 0 | 35 | 0 | 0 | 0 | 8 | 43 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 0 | 6 | 0 | 0 | 357 | 10 | 373 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 10 | 60 | 0 | 0 | 0 | 0 | 70 |
| 1.u. Quail (Coturnix coturnix) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.v. Other birds (other Aves) | 3913 | 61303 | 152 | 683 | 63959 | 14181 | 144191 |
| 1.w. Reptiles (Reptilia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.x. Amphibians (Amphibia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.y. Fish (Pisces) | 1222 | 3446 | 0 | 0 | 3971 | 590 | 9229 |
| 1.z. TOTAL | 47509 | 617731 | 205 | 38965 | 1054404 | 95739 | 1854553 |

(*) France reporting for 2004

Examples: $\quad 5.2$ - France is testing due to a UK (or FR) specific requirement Note:
5.3-UK is testing according to EC legislation
5.4-Spain is testing due to a Hungarian requirement Example:
5.5 - Sweden is testing due to a US specific requirement
5.6 - Germany is testing due to a Czech requirement (also an EC requirement)
columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

## III.7. Results of EU harmonized Table 6: Origin of regulatory requirements for animals used in toxicological and other safety evaluations

III.7.1. The data on the origin of regulatory requirements for animals used in toxicological and other safety evaluations

The consolidated table for the 25 Member States reporting data on animals used in toxicological and other safety evaluations in relation to the origin of regulatory requirements (EU Table 6) is presented in Table 6.1 at the end of this chapter.

## III.7.2. Treatment and interpretation of the data

It can be observed that the use of animals for regulatory requirements in the area of toxicological or other safety evaluation presented in Figure 6.1 follows a similar pattern to that of the use for regulatory purposes in human medicine, dentistry and in veterinary medicine presented in the Figure 5.1 in the previous chapter.

As pointed out earlier, the number of animals used in toxicological or other safety evaluation represents $8 \%$ of the total number of animals used for experimental purposes in the EU.

Figure 6.1
Percentages of animals used for regulatory requirements for toxicological and other safety evaluation


Animals used to simultaneously satisfy regulatory requirements from several pieces of legislation covered more than half of the animals used in this area ( $54,2 \%$ ). The testing required under the EU legislation including the European Pharmacopoeia accounts for the second highest percentage in this area namely $23 \%$.

It should be underlined that the proportional decrease of the numbers of animals used for toxicological and other safety evaluation since the last report, from $10 \%$ to $8 \%$, represents at the same time a decrease of about 40,000 animals. The number of animals used "no regulatory requirements" decreased since the last report from 114,000 to 90,000 animals, a drop of 24,000 animals.

Member States who were asked to provide some further explanation as to the reasons for this clear decrease of animals used for no regulatory requirements compared to previous reports, indicated that the decrease was partially attributed to use of alternative in vitro methods and invertebrate animals. For example, safety pharmacological tests such as those used for supplementary batch control by the European Pharmacopoeia. In order to understand what is meant by the term 'no regulatory requirements', for example some Member States indicated that legal obligations to ensure quality and safety of imported drugs would be reported under this category.

The testing to satisfy national legislation specific to a single Member State showed a decrease in this report with respect to the previous one but it represents about 15,500 animals i.e. $1,5 \%$ of the total number used for toxicological and other safety evaluation.

Table 6.1: Number of animals used in toxicological and other safety evaluations
Regulatory requirements versus species
Data of 2005*

| 6.1. Species | 6.2. National legislation specific to a single EC Member State1) | 6.3. EC legislation including European Pharmacopoeia (requirements) | 6.4. Member Country of Council of Europe (but not EC) legislation2) | 6.5. Other legislation | 6.6. Any combination of 5.2/5.3/5.4/5.5 | 6.7. No regulatory requirements | 6.8.Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 39972 | 104143 | 170 | 15039 | 189776 | 37144 | 386244 |
| 1.b. Rats (Rattus norvegicus) | 19368 | 61953 | 670 | 15875 | 224860 | 25772 | 348498 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 1009 | 21189 | 70 | 2052 | 27849 | 1329 | 53498 |
| 1.d. Hamsters (Mesocricetus ) | 0 | 182 | 0 | 0 | 1204 | 284 | 1670 |
| 1.e. Other Rodents (other Rodentia) | 0 | 300 | 0 | 0 | 0 | 583 | 883 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 1398 | 9462 | 13 | 2653 | 23162 | 2420 | 39108 |
| 1.g. Cats (Felis catus) | 166 | 46 | 0 | 6 | 4 | 23 | 245 |
| 1.h. Dogs (Canis familiaris) | 977 | 1919 | 0 | 520 | 10842 | 324 | 14582 |
| 1.i. Ferrets (Mustela putorius furo) | 0 | 0 | 0 | 0 | 41 | 0 | 41 |
| 1.j. Other Carnivores (other Carnivore) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.k. Horses, donkeys and cross breds (Equidae) | 0 | 5 | 0 | 0 | 25 | 10 | 40 |
| 1.I. Pigs (Sus) | 57 | 1150 | 0 | 132 | 1642 | 266 | 3247 |
| 1.m. Goats (Capra) | 0 | 26 | 0 | 0 | 3 | 44 | 73 |
| 1.n. Sheep (Ovis) | 4 | 120 | 0 | 0 | 191 | 108 | 423 |
| 1.0. Cattle (Bos) | 12 | 320 | 0 | 15 | 203 | 107 | 657 |
| 1.p. Prosimians (Prosimia) | 0 | 97 | 0 | 0 | 0 | 0 | 97 |
| 1.q. New World Monkeys (Ceboidea) | 0 | 0 | 0 | 0 | 599 | 51 | 638 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 0 | 304 | 0 | 488 | 5312 | 153 | 6257 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 0 | 15 | 0 | 0 | 0 | 0 | 15 |
| 1.u. Quail (Coturnix coturnix) | 0 | 2124 | 0 | 0 | 1037 | 25 | 3186 |
| 1.v. Other birds (other Aves) | 5519 | 4787 | 0 | 522 | 38262 | 1654 | 50744 |
| 1.w. Reptiles (Reptilia) | 12 | 0 | 0 | 0 | 0 | 0 | 12 |
| 1.x. Amphibians (Amphibia) | 542 | 0 | 0 | 0 | 0 | 0 | 542 |
| 1.y. Fish (Pisces) | 27338 | 34565 | 312 | 3029 | 31210 | 19120 | 115574 |
| 1.z. TOTAL | 96374 | 242707 | 1235 | 40331 | 556222 | 89417 | 1026286 |

(*)France reporting for 2004

Examples: $\quad 6.2$ - France is testing due to a UK (or FR) specific requirement
6.3 - UK is testing according to EC legislation
6.4 - Spain is testing due to a Hungarian requirement
6.5 - Sweden is testing due to a US specific requirement
6.6-Germany is testing due to a Czech requirement (also an EC requirement)

Note: columns 6.2-6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol
Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

## III.8. Results of EU Table 7: $\underline{\text { Animals used in toxicity test for toxicological and other safety }}$ evaluations

III.8.1. The data on animals used in toxicity test for toxicological and other safety evaluations

The consolidated table for the 25 Member States reporting on animals used in toxicity tests for the purpose of toxicological and other safety evaluations of products (EU Table 7) is presented in Table 7.1 at the end of this chapter.

## III.8.2. Treatment and interpretation of the data

For the convenience of the presentation of results some of the toxicity tests of Table 7.1 have been grouped according to systemic and local toxicity and CMR effects in Table 7.2 of this report. A graph showing the percentage of animals used per toxicity test groups in 2005 is presented in Figure 7.1.

Figure 7.1
Percentages of animals used in toxicity tests for toxicological and other safety evaluation


As pointed out in the previous chapter, the number of animals used in toxicological and other safety evaluation represents $8 \%$ of the total number of animals used for experimental purposes.

It can be seen in Figure 7.1 that the largest percentage of use of animals is due to acute and subacute toxicity tests $42 \%$ in 2005. Taking also into account sub-chronic and chronic toxicity, the percentage of animals used in short and long term systemic toxicity testing accounts for $53 \%$ of the experimental animals used in this area.

About $17,5 \%$ of animals were used for testing carcinogenicity, mutagenicity and toxicity to reproduction in 2005. Another important category of use of animals in 2005 is for "other tests" with $22,3 \%$. Breaking down further the category 'other', Member States reported testing in areas such as biological screening for pharmaceutical, healthcare and veterinary products. This includes neurotoxicity, toxicokinetics, testing of acute dermal toxicity, testing of biological evaluation of medical devices: Intracutan testing of reactivity on rabbits, study into penetration of nanoparticle through tissue and their biocompatibility, study into evaluation of sensitization potential of dyestuffs used in textile industry and pharmacological studies included in safety tests.

By looking both in numbers and relative percentages of use of animals in comparison to the previous reports there are three noticeable changes:

One can observe a continuous increase over the last three reports of the proportion of animals used for acute and sub-acute tests ranging from: $32 \%, 36 \%$ to $42 \%$ respectively. This represents in animal numbers an increase of 39,000 animals since the last report of 2002. Member States attributed the increase in part to several phases in new product development and new legislation for example requiring that all generic substances should be tested.

On the other hand one can observe a steady decrease over the last three reports of the proportion of animals used for toxicity tests to reproduction going down from: $15 \%, 12 \%$ to $10 \%$ respectively.

Another important decrease in the proportion of animals used is the decrease from 4,5\% to $1,2 \%$ of animals used in toxicity test to aquatic vertebrates.

Some Member States presume that the decrease in regulatory testing can indeed be attributed to alternative methods but others think that replacement methods have a much greater impact on R\&D than on regulatory requirements. They point out that the statistics drawn up annually include re-use of animals which plays an important role.

Table 7.1: Number of animals used in toxicological and other safety evaluations
Type of tests versus species
Data of 2005*

| 7.1. Species | 7.2. Acute and sub-acute toxicity testing methods (including limit test) |  |  |  | 7.4. Skin sensitis ation | 7.5. Eye irritation | 7.6. Subchronic and chronic toxicity | 7.7. <br> Carcinogenicity | $7.8$ <br> Developmental toxicity | $7.9 .$ <br> Mutagenicity | 7.10. Reproductive toxicity | 7.11. <br> Toxicity to aquatic vertebra-tes not included in other columns | 7.12.Other | $\begin{aligned} & \hline 7.13 . \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | $\begin{aligned} & \text { 7.2.1. } \\ & \text { LD50, } \\ & \text { LC50 } \end{aligned}$ | 7.2.2. <br> Other <br> lethal methods | 7.2.3. Non lethal clinical signs methods |  |  |  |  |  |  |  |  |  |  |  |
| 1.a. Mice (Mus musculus) | 33024 | 86669 | 68682 | 2805 | 21350 | 0 | 25550 | 19624 | 2612 | 19479 | 908 | 0 | 105541 | 386244 |
| 1.b. Rats (Rattus norvegicus) | 19756 | 18614 | 78707 | 1156 | 303 | 142 | 65466 | 22400 | 23886 | 15727 | 51518 | 0 | 50829 | 348504 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 1415 | 993 | 17572 | 2144 | 22184 | 0 | 628 | 0 | 0 | 0 | 0 | 0 | 8556 | 53492 |
| 1.d. Hamsters (Mesocricetus) | 0 | 64 | 603 | 0 | 0 | 0 | 38 | 0 | 0 | 20 | 0 | 0 | 945 | 1670 |
| 1.e. Other Rodents (other Rodentia) | 56 | 142 | 300 | 0 | 0 | 0 | 300 | 0 | 0 | 0 | 0 | 0 | 40 | 838 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 36 | 49 | 2944 | 5130 | 52 | 4033 | 1693 | 0 | 8078 | 31 | 4640 | 0 | 12467 | 39153 |
| 1.g. Cats (Felis catus) | 0 | 0 | 108 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 114 | 222 |
| 1.h. Dogs (Canis familiaris) | 182 | 659 | 5170 | 0 | 0 | 0 | 6998 | 0 | 0 | 0 | 29 | 0 | 1567 | 14605 |
| 1.i. Ferrets (Mustela putorius furo) | 0 | 0 | 41 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 41 |
| 1.j. Other Carnivores (other Carnivore) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.k. Horses, donkeys and cross breds (Equidae) | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 30 | 40 |
| 1.I. Pigs (Sus) | 8 | 49 | 304 | 8 | 0 | 0 | 971 | 0 | 89 | 0 | 100 | 0 | 1718 | 3247 |
| 1.m. Goats (Capra) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 39 | 39 |
| 1.n. Sheep (Ovis) | 0 | 0 | 32 | 0 | 0 | 0 | 0 | 0 | 35 | 0 | 37 | 0 | 353 | 457 |
| 1.o. Cattle (Bos) | 0 | 0 | 73 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 584 | 657 |
| 1.p. Prosimians (Prosimia) | 0 | 0 | 60 | 0 | 0 | 0 | 32 | 0 | 0 | 0 | 0 | 0 | 5 | 97 |
| 1.q. New World Monkeys (Ceboidea) | 0 | 85 | 222 | 0 | 0 | 0 | 185 | 0 | 90 | 0 | 0 | 0 | 68 | 638 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 0 | 1 | 2014 | 0 | 0 | 33 | 3406 | 0 | 131 | 0 | 187 | 0 | 485 | 6257 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 15 | 15 |
| 1.u. Quail (Coturnix coturnix) | 2253 | 348 | 105 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 480 | 0 | 0 | 3186 |
| 1.v. Other birds (other Aves) | 1671 | 260 | 11403 | 1000 | 0 | 0 | 158 | 0 | 0 | 0 | 128 | 0 | 36124 | 50744 |
| 1.w. Reptiles (Reptilia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 12 | 12 |
| 1.x. Amphibians (Amphibia) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 42 | 0 | 0 | 0 | 500 | 542 |
| 1.y. Fish (Pisces) | 54830 | 10449 | 11146 | 0 | 0 | 0 | 6443 | 0 | 5484 | 226 | 5284 | 12675 | 9037 | 115574 |
| 1.z. TOTAL | 113231 | 118382 | 199496 | 12243 | 43889 | 4208 | 111868 | 42024 | 40447 | 35483 | 63311 | 12675 | 229029 | 1026286 |

(*) France reporting for 2004

Table 7.2: Grouping of certain type of tests on animals of table 7.1

| 7.1. Species | Acute and sub-acute toxicity testing methods (including limit test) | Irritation /sensitization tests | Sub- chronic and chronic toxicity | Mutagenicity and carcinogenicity | Reproductive and developmental toxicity | Toxicity to aquatic vertebrates not included in other columns | other | Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 188375 | 24155 | 25550 | 39103 | 3520 | 0 | 105541 | 386244 |
| 1.b. Rats (Rattus norvegicus) | 117077 | 1601 | 65466 | 38127 | 75404 | 0 | 50829 | 348504 |
| 1.c. Guinea-Pigs (Cavia porcellus) | 19980 | 24328 | 628 | 0 | 0 | 0 | 8556 | 53492 |
| 1.d. Hamsters (Mesocricetus) | 667 | 0 | 38 | 20 | 0 | 0 | 945 | 1670 |
| 1.e. Other Rodents (other Rodentia) | 498 | 0 | 300 | 0 | 0 | 0 | 40 | 838 |
| 1.f. Rabbits (Oryctolagus cuniculus) | 3029 | 9215 | 1693 | 31 | 12718 | 0 | 12467 | 39153 |
| 1.g. Cats (Felis catus) | 108 | 0 | 0 | 0 | 0 | 0 | 114 | 222 |
| 1.h. Dogs (Canis familiaris) | 6011 | 0 | 6998 | 0 | 29 | 0 | 1567 | 14605 |
| 1.i. Ferrets (Mustela putorius furo) | 41 | 0 | 0 | 0 | 0 | 0 | 0 | 41 |
| 1.j. Other Carnivores (other Carnivore) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.k. Horses, donkeys and cross breds (Equidae) | 10 | 0 | 0 | 0 | 0 | 0 | 30 | 40 |
| 1.I. Pigs (Sus) | 361 | 8 | 971 | 0 | 189 | 0 | 1718 | 3247 |
| 1.m. Goats (Capra) | 0 | 0 | 0 | 0 | 0 | 0 | 39 | 39 |
| 1.n. Sheep (Ovis) | 32 | 0 | 0 | 0 | 72 | 0 | 353 | 457 |
| 1.0. Cattle (Bos) | 73 | 0 | 0 | 0 | 0 | 0 | 584 | 657 |
| 1.p. Prosimians (Prosimia) | 60 | 0 | 32 | 0 | 0 | 0 | 5 | 97 |
| 1.q. New World Monkeys (Ceboidea) | 307 | 0 | 185 | 0 | 90 | 0 | 68 | 638 |
| 1.r. Old World Monkeys (Cercopithecoidea) | 2015 | 33 | 3406 | 0 | 318 | 0 | 485 | 6257 |
| 1.s. Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. Other Mammals (other Mammalia) | 0 | 0 | 0 | 0 | 0 | 0 | 15 | 15 |
| 1.u. Quail (Coturnix coturnix) | 2706 | 0 | 0 | 0 | 480 | 0 | 0 | 3186 |
| 1.v. Other birds (other Aves) | 13334 | 1000 | 158 | 0 | 128 | 0 | 36124 | 50744 |
| 1.w. Reptiles (Reptilia) | 0 | 0 | 0 | 0 | 0 | 0 | 12 | 12 |
| 1.x. Amphibians (Amphibia) | 0 | 0 | 0 | 0 | 42 | 0 | 500 | 542 |
| 1.y. Fish (Pisces) | 76425 | 0 | 6443 | 226 | 10768 | 12675 | 9037 | 115574 |
| 1.2. TOTAL | 431109 | 60340 | 111868 | 77507 | 103758 | 12675 | 229029 | 1026286 |

## III.9. Results of EU Table 8: Type of toxicity tests carried out for toxicological and other safety evaluations of products

## III.9.1. The data on type of toxicity tests carried out for toxicological and other safety evaluations of products

The consolidated table for the type of toxicity tests carried out for toxicological or other safety evaluations of products, for the 25 Member States reporting (EU Table 8) is presented in Table 8.1 of this report. There are discrepancies between the total numbers of animals per types of tests in Table 7 in comparison with the total numbers of animals per types of tests of Table 8. Logically these should be the same. These discrepancies originate from 10 Member States; however, when the data was submitted no explanation was given as to the reasons. The overall total number of animals for toxicological and other safety evaluations remains coherent.

## III.9.2. Treatment and interpretation of the data

As pointed out earlier it is important to keep in mind that animals used in toxicological and other safety evaluation represent $8 \%$ of the total number of animals used for experimental purposes. The treatment and interpretation of the data on animals used for toxicity tests with regard to the type of products has not been done in the previous reports due to inconsistencies in the data in the past. The results in this area are therefore analysed and compared in this report for the first time.

Figure 8.1 represents the percentages of the number of animals used in toxicological testing or other safety evaluations in relation to the type of products or purposes. In order to give a better graphical presentation of the results, some type tests have been grouped according to systemic and local toxicity and carcinogenic, mutagenic and toxicity to reproduction effects in Table 8.2 of this report.

Figure 8
Percentages of animals used for toxicity tests for toxicological and other safety evaluation by types of products


Figure 8.1 shows a decrease in the proportion of animals used in acute and sub-acute toxicity tests in comparison with other tests when moving down in the graph for products used A) for human medicine, dentistry and veterinary medicine, B) for agriculture, C) for industry, D) for household, E) for cosmetics, F) for additives in food consumption and G) for additives in food for animal consumption. However, the animals used in acute and sub-acute toxicity tests for other toxicological and safety evaluations would benefit from further analysis.

Contrary to acute and sub-acute toxicity one can observe an increase in the proportion of animals used for irritation and sensitization tests. While further down the graph amongst the four first types of products, a maximum amount of testing takes place for products used in cosmetics and toiletries.

The proportion of animals used in sub-chronic and chronic testing seems to follow the same pattern as for irritation sensitization tests with the highest proportion used for D ) household products and F ) additives in food for human consumption.

The pattern of use of carcinogenicity, mutagenicity and toxicity to reproduction tests is rather scattered between the different types of products and more difficult to interpret.

The proportion of animals used for G) additives in food for animal consumption is governed by about $90 \%$ by other tests. This group would benefit from further analysis.

Table 8.1: Number of animals used in toxicological and other safety evaluations Type of tests versus products

Data of 2005*

| 8.1. Products | 8.2. Acute and sub-acute toxicity testing methods (including limit test) |  | e toxicity limit test) <br> 8.2.3. Non lethal clinical signs methods | 8.3. Skin irritation | 8.4. Skin sensitisat ion | 8.5. Eye irritatio n | 8.6. Subchronic and chronic toxicity | $8.7$ <br> Carcinogenicity | 8.8. Develop - mental toxicity | $8.9$ <br> Mutagenicity | 8.10. Reproductive toxicity | 8.11. Toxicity to aquatic vertebra-tes not included in other columns | $\begin{aligned} & 8.12 . \\ & \text { Other } \end{aligned}$ | $\begin{aligned} & \hline 8.13 . \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 8.a. Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 18820 | 38091 | 155459 | 4097 | 15296 | 1452 | 67651 | 26589 | 18238 | 21005 | 30788 | 3419 | 127284 | 528189 |
| 8.b. Products/ substances used or intended to be used mainly in agriculture | 21368 | 5956 | 11467 | 872 | 6486 | 654 | 12535 | 3100 | 10158 | 1831 | 12599 | 1847 | 8687 | 97560 |
| 8.c. Products/ substances used or intended to be used mainly in industry | 18963 | 4047 | 13416 | 4743 | 9264 | 1111 | 13177 | 2644 | 3230 | 8371 | 10043 | 2136 | 5684 | 96829 |
| 8.d. Products/ substances used or intended to be used mainly in the household | 20 | 18 | 11 | 48 | 154 | 70 | 568 | 3 | 0 | 51 | 0 | 0 | 276 | 1219 |
| 8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries | 0 | 349 | 684 | 469 | 2222 | 300 | 966 | 0 | 368 | 213 | 0 | 0 | 0 | 5571 |
| 8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption | 6 | 40 | 1283 | 3 | 98 | 3 | 1767 | 0 | 0 | 239 | 1210 | 0 | 572 | 5221 |
| 8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption | 0 | 907 | 239 | 30 | 0 | 0 | 160 | 24 | 0 | 0 | 423 | 0 | 31692 | 33475 |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns | 32120 | 9894 | 5959 | 0 | 0 | 0 | 3793 | 7045 | 4541 | 594 | 5393 | 6524 | 7885 | 83748 |
| 8.i. Other toxicological or safety evaluations | 20974 | 58282 | 8840 | 668 | 4921 | 478 | 23062 | 1459 | 2756 | 4836 | 2088 | 4593 | 41517 | 174474 |
| 8.j. TOTAL | 112271 | 117584 | 197358 | 10930 | 38441 | 4068 | 123679 | 40864 | 39291 | 37140 | 62544 | 18519 | 223597 | 1026286 |

Table 8.2: Number of animals used in toxicological and other safety evaluation per types of products

| 8.1. Products | Acute and sub-acute toxicity testing methods (including limit test) | Irritation/sensitization tests | Sub- <br> chronic <br> and <br> chronic <br> toxicity | Mutagenicity and carcinogenicity | Reproductive and developmental toxicity | Toxicity to aquatic <br> vertebra-tes not included in other columns | Other | Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 8.a. Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 212370 | 20845 | 67651 | 47594 | 49026 | 3419 | 127284 | 528189 |
| 8.b. Products/ substances used or intended to be used mainly in agriculture | 38791 | 8012 | 12535 | 4931 | 22757 | 1847 | 8687 | 97560 |
| 8.c. Products/ substances used or intended to be used mainly in industry | 36426 | 15118 | 13177 | 11015 | 13273 | 2136 | 5684 | 96829 |
| 8.d. Products/ substances used or intended to be used mainly in the household | 49 | 272 | 568 | 54 | 0 | 0 | 276 | 1219 |
| 8.e. Products/ substances used or intended to be used mainly as cosmetics or toiletries | 1033 | 2991 | 966 | 213 | 368 | 0 | 0 | 5571 |
| 8.f. Products/ substances used or intended to be used mainly as additives in food for human consumption | 1329 | 104 | 1767 | 239 | 1210 | 0 | 572 | 5221 |
| 8.g. Products/ substances used or intended to be used mainly as additives in food for animal consumption | 1146 | 30 | 160 | 24 | 423 | 0 | 31692 | 33475 |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns | 47973 | 0 | 3793 | 7639 | 9934 | 6524 | 7885 | 83748 |
| 8.i. Other toxicological or safety evaluations | 88096 | 6067 | 23062 | 6295 | 4844 | 4593 | 41517 | 174474 |
| 8.j. TOTAL | 427213 | 53439 | 123679 | 78004 | 101835 | 18519 | 223597 | 1026286 |

# PART B: DATA AND SUMMARY OF THE COMMENTS SUBMITTED BY THE MEMBER STATES 


#### Abstract

AUSTRIA

\section*{Statistical data submitted}

The statistical data have been submitted by the "Bundesministerien für Gesundheit und Frauen- Land und Forstwirtshaft, Umwelt und Wasserwirtschaft - Wirtschaft und Arbeit - Bildung, Wissenschaft und Kultur" (Federal Ministries for Health and Women -Agriculture Forestry, the Environment and Water Mangement - Economic Affairs and Labour - Education, Science and Culture).


## Comments from the Austrian authorities

In accordance with Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes, animal experiments in Austria are regulated by the Tierversuchsgesetz (Animal Experiments Act) (Federal Law of 27 September 1989 on experiments using live animals, Federal Law Gesetz, (BGBL. No 501/1989, as most recently amended by Federal Law No.162/2005. Responsibility for enforcing the Animal Experiments Act in Austria rests with the Federal Minister for Health and Women, the Federal Minister for Economic affairs and Labour, the Federal Minister for Agriculture, Forestry, the Environment and Water Management and the Federal Minister for Education, Science and Culture.

Animal experiments are permitted in Austria only if the stringent requirements of the Animal Experiments Act are met and only for one of the following reasons:
a) for research and development
b) for vocational training
c) for medical diagnosis and therapy
d) for testing natural or synthetic materials, preparations or products
e) for detecting environmental risks
f) for obtaining materials

## Animal experiments may only be carried out providing that

1. There is a justified interest in carrying out the experiment, i.e.
a) for preventing, detecting or curing diseases in human beings or animals,
b) for detecting or influencing physiological conditions or functions in human beings or animals,
c) for securing scientific knowledge
d) for providing vocational training or,
e) for obviating environmental risks, and providing that
2. The objectives pursued by the experiments cannot be achieved by other methods or procedures (alternative techniques) or, in the case of vocational training, by using other teaching aids, in particular films or other audiovisual media.

## Experiments on animals are never permitted,

a) if the results of a similar experiment are de facto and de jure accessible and no justified doubts exist as to the accuracy and meaningfulness of the said results,
b) if no further or new knowledge is likely to come from the experiment,
c) if the experiment is not necessary, even for control purposes, or
d) if the results of an animal experiment carried out in Austria or abroad are de facto or de jure accessible, no justified doubts exist regarding the accuracy and meaningfulness of those results and they are officially recognised in Austria on the basis of the relevant statutory provisions.

In addition to the above, the competent Federal Ministers can issue regulations determining which methods are no longer permitted for animal experiments since they are outdated in the light of scientific progress achieved. By way of example, the "LD-50" test has been banned in Austria since 1992.

## The Animal Experiments Act directly prohibits the following:

- animal experiments for cosmetic purposes (since 1999), and
- animal experiments involving the Great Apes (since 1. 1. 2006).


## Guiding principles

The Animal Experiments Act also contains guiding principles for all scientists and other personnel involved in animal experiments and these are binding, also on the competent authorities. Particular features of these are that:

Animal experiments must be consistent with the principles of scientific research and the hypothesis being tested and the procedure selected must be reasonable in the light of acknowledged scientific progress. Animal experiments are to be conducted with a view to obtaining as much new knowledge as possible.

The meaningfulness and practicability of model animal experiments are to be continuously and critically assessed with a view to reducing the number of animal experiments and increasing the use of alternative techniques, adapting them to reflect acknowledged scientific progress. Results obtained from behavioural research and animal experiments as well as developments in measurement and laboratory techniques are to be taken into account in order to minimize the stress that experimental animals undergo.

All persons involved in carrying out animal experiments are responsible in ethical and scientific terms for the tasks they are required to undertake. It is the duty of every scientist to assess the necessity and appropriateness of the animal experiment that he has planned, headed and completed, weighing them against the stress to which the animals are subjected.

Accordingly, Austria's Animal Experiments Act has express provision, as a legal requirement, for applying the principles of the ' 3 Rs' (reduction, refinement, replacement).

As regards the keeping of experimental animals (caring for and housing the animals) Austria's legislation on animal experiments has not only fully transposed the guidelines set out in Annex II to Article 5 of Directive 86/609/EEC by law and regulation, but in the interests of animal welfare and of considerably improving the standards of animal husbandry, it has also made these provisions legally binding.

## Promoting alternatives to animal experiments as a legal obligation

The Federal Ministers responsible for enforcing the Animal Experiments Act (see above) are required by law (the Animal Experiments Act) to promote the development of alternative methods and procedures that do not involve animal experiments (see above) in line with the relevant Federal financial legislation and progress in science and to promote alternative methods and procedures. The aim is to develop alternative methods that are scientifically meaningful and which make it possible to reduce the number of experimental animals and the stress to which they are exposed or even to make animal experiments wholly redundant.

Promoting the objective of the 3 Rs is thus an express component of Austria's Animal Experiments Act, the aim being to improve the protection of animals. Over the last decade more than EUR 2.5 million has been spent on researching and developing alternatives to animal experiments, in particular on the part of the Federal Ministry for Education, Science and Culture. Austria also supports, wherever possible, the development, validation and use of alternatives to animal experiments at international level, in particular in the context of the EU and the OECD.

It should also be remembered in this connection that conferences on animal experiments and alternative methods have in the past been organised under Austrian Presidency. By way of example, in November 1998 a conference was organised in conjunction with the European Commission on the subject of "Implementation of the 3 Rs - Objectives for the EU and for science and industry". The aim of this symposium was to promote the implementation of the 3Rs also at EU level. The symposium was attended by the competent authorities from all EU Member States as well as, for the first time, representatives of the third countries that have meanwhile become EU Member States. One of the resolutions adopted at this symposium was forwarded to the Council of Ministers of the EU and to the European Commission for further action. At the beginning of July 2006 the 13th Congress on Alternatives to Animal Testing (meanwhile a tradition) was held in Linz under the patronage of the Austrian EU Presidency offering a much-acclaimed scientific programme on alternatives to animal experiments.

During its EU Presidency in the first half of 2006 Austria sought, in addition to the above, to secure a decision of the Council on the position of the European Community with regard to the proposal to amend Annex A of the European Convention on protecting animals used for experiments and other scientific purposes (see Council of the European Union 7643/06 Legislative Acts and other legal instruments, adopted by the Council on 10 April 2006). As a result, it was possible to ensure that at the fourth multilateral hearing of the parties to this European Convention the European Commission, on behalf of the European Community, was able to support and adopt this revised Appendix A of the Convention that contained guidelines for the housing and care of such animals.

## Statistics on animal experiments

Statistics on animal experiments in Austria are produced in accordance with Article 13 of Directive 86/609/EEC pursuant to § 16 of the Animal Experiments Act and the Regulation on Statistics relating to Animal Experiments (Tierversuchsstatistik-Verordnung), which is based on it (BGB1. II No 199/2000), and sets out the standardised statistics for animal experiments which are to be produced annually and be of a binding nature. No later than 1 March every year persons responsible for carrying out animal experiments must submit to the ministry responsible for enforcing the Animal Experiments Act their statistical data relating to their animal experiments during the previous year. The following information is to be provided:
a) the number and type of experimental animals used overall plus the origin and number, with breakdown, of the animals used,
b) the number and types of animals used (types of experimental animals, with breakdown),
c) the number and types of experimental animals used for toxicological and other safety tests,
d) the number and types of experimental animals used for tests on human and animal diseases,
e) the number and types of experimental animals used in the manufacture and quality control of products and equipment for human medicine, dentistry and veterinary medicine including, where appropriate, an indication of the relevant statutory provisions,
f) the number and types of animals used for toxicological and other safety tests, where appropriate with an indication of the relevant statutory provisions as well as the type of test (technique) and products or materials (types of products or materials).

The Federal Ministers responsible for enforcing the Animal Experiments Act are required to produce, by 30 June of every year, a summary report on animal experiment statistics relating to the previous year and publish it in Austria's Official Journal (Amtsblatt zur Wiener Zeitung).

## Statistics on animal experiments for 2005

Compared with the previous year there were $10 \%$ fewer animal experiments

## Compared with other countries there were few animal experiments

As shown in Austria's Official Journal dated 29 June 2006, the 2005 animal experiment statistics show that in 2005 a total of 167,312 animals were used in experiments. This is the lowest figure since 2001.

Compared with earlier years, this indicates a further reduction in the number of animal experiments in Austria as a whole within the "fluctuating" numbers of the past few years (ranging from 160,000 to $200,000)$. The number of experimental animals is therefore again significantly lower than those for the previous years; for example, in 1996 the number totalled was 203,825 , in 1993 it was 272,371 and in 1992 it was 304,308 . Compared with 1991 (the first year of statistical coverage) the number of animals used has remained low (at less than $35 \%$ ). In that year there were 482,166 animals used for experiments, in other words numbers have dropped since then by more than $65 \%$.


The full statistics on animal experiments with all tables produced by the Federal Ministries responsible for enforcing the Animal Experiments Act, namely the Federal Ministry for Health and Women, the Federal Ministry for Economic affairs and Labour, the Federal Ministry for Agriculture, Forestry, the Environment and Water Management and the Federal Ministry for Education, Science and Culture, can be found on the home page of the Federal Ministry for Education, Science and Culture using the following link http://www.bmbwk.gv.at/tierversuche/statistik2005

## Animal experiments for human beings and animals

The figures for animal experiments in 2005 - primarily on mice and rats - can be explained in general terms by an increase in biomedical research and a rise in the number of biomedical and bioscientific as well as pharmaceutical firms conducting research, in particular research and development of products for human and veterinary medicine, along with the manufacture and quality control of vaccines that are manufactured for the world market to control major diseases, primarily cancer, leukaemia, diseases of the heart and circulation and AIDS. Cancer research concentrates primarily on the development of improved and more effective therapies that are less stressful for patients.

The figures for animal experiments in the field covered by the Federal Ministry for Health and Women have their origin in an increase in the number of samples taken for the (required) quality control as well as the establishment of new standards for pharmaceutical products undergoing development and new research projects, for example the development and production of human vaccines and therapeutic products. The greater emphasis placed on the development of medical and pharmaceutical medicaments means that despite every effort to find alternative methods, animal experiments are, with a view to protecting the health and safety of human beings and animals, indispensable as a preliminary stage prior to any decision on clinical trials on humans.

Lastly, animal experiments are necessary for the animal health as such, i.e. for the development of pharmaceutical products for animals by means of clinical tests on and for animals and this has meant that slightly more dogs and cats have been used. Animal experiments are also necessary for the development of diagnostic and therapeutic measures for animals as well, examples being procedures
for the early detection of cardiac insufficiency in cats or clinical studies on vaccines to control infectious diseases in dogs.

## Rats and Mice are the primary experimental animals

In 2005 of the 167312 animals that were used for experiments in Austria, 140554 (compared with 158361 in 2004 and 148.382 in 2003) were rats and mice,

3140 (2004: 4158 and 2003: 4 958) were guinea pigs; 18439 (2004: 20654 and
2003: 13 928) were rabbits, 1664 were useful domestic farm animals, (sheep, goats, pigs, and cattle etc.), 1011 were birds, 992 were fish, 865 were amphibians, 85 were dogs (2004: 155 and 2003: 139) and 12 (2004: 18 and 2003: 22) were cats.

## No animal experiments for cosmetics

The statutory ban on the use of animals for experiments for cosmetics that has been in place since 1999 has meant that in accordance with $\S(5)$ of the Animal Experiments Act it goes without saying that no animal experiments were conducted in Austria for cosmetics. Austria is in this respect particularly committed to protecting Europe's animals.

## No primates for experimental purposes

## Statutory ban on experiments on or involving primates.

It can happily be reported that in 2005 Austria continued to forgo the use of primates for animal experiments. This is consistent with the pan-European call for restricting such animal experiments as far as possible and replacing them totally in line with "scientific progress". In 2005 the Federal Ministry for Education Science and Culture resubmitted - on the basis of a Resolution of the National Council of December 2004 and following a general examination - a Parliamentary Bill to the National Council for a statutory ban on animal experiments involving primates, which it adopted in December 2005. The provision entered into force on 1 January 2006.

## Austria's figures for animal experiments are comparatively low in international terms

With a total of 167.312 experimental animals (primarily mice and rats) used in 2005, Austria had significantly fewer animal experiments in international terms as well as in terms of the animals used for such experiments. By way of example, neighbouring Switzerland used 550000 animals for experimental purposes in 2005.

These comparatively low figures for the animals used in animal experiments - accounting for a $65 \%$ drop since 1991 - can be explained by at least two inter-related lines of development in relation to animal experiments:

## 1.) The Three "Rs"

Firstly, 'Reduction, Refinement, Replacement' in relation to animal experiments conducted by scientists, researchers and practical scientists themselves as well as ensuring, as far as possible, the availability of alternative methods to replace animal experiments as this is expressly required by Austria's Animal Experiments Act.

## 2) Restrictions on the authorization of animal experiments and the promotion of alternative techniques

Secondly, a more restrictive approach on the part of all of the competent authorities to the authorisation of animal experiments in line with the strict requirements of the Animal Experiments Act, which has undergone further improvement since 1999/2000, as have animal experiment regulations in Austria, in accordance with which animal experiments are only permitted subject to very severe restrictions and can be expressly authorised only if the objectives pursued in the experiment cannot be achieved by other methods or procedures (alternative techniques).

Last but not least, it is the public motivation prompted by the award of national prizes or promoting research projects for alternative techniques as well as propagating at national and international level the use of alternatives to animal experiments that has led to an enhanced awareness of responsibility on the part of the general public with regard to science/research involving animal experiments.

## Greater effort to promote the development of alternatives to animal experiments

In September of last year the Federal Ministry for Education, Science and Culture in agreement with all the other Federal Ministries responsible for enforcing the Animal Experiments Act (Federal Ministries for Health and Women, for Economic Affairs and Labour and for Agriculture and Forestry, the Environment and Water) renewed its public call for the submission of research projects targeting alternatives to animal experiments, the aim of which is to provide greater support for alternatives to animal experiments which will be determined ultimately by the number and scale of the projects that are submitted.

It was only last year that the public call for projects by the Federal Ministry for Education Science and Culture was again used to award a national prize for alternatives to animal experiments, in other words particular recognition by the State of scientific results already achieved.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | $1.5$ <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 128634 | 28469 | 99702 | 184 | 279 | 59 |
| 1.b. | Rats (Rattus norvegicus) | 11920 | 5278 | 6642 | 0 | 0 | 47 |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 3149 | 340 | 2809 | 0 | 0 | 0 |
| 1.d. | Hamsters (Mesocricetus ) | 117 | 0 | 117 | 0 | 0 | 0 |
| 1.e. | Other Rodents (other Rodentia) | 107 | 60 | 25 | 0 | 22 | 0 |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 18439 | 11165 | 7253 | 0 | 21 | 41 |
| 1.g. | Cats (Felis catus) | 12 | 0 | 2 | 0 | 10 | 10 |
| 1.h. | Dogs (Canis familiaris) | 85 | 67 | 0 | 0 | 18 | 7 |
| 1.i. | Ferrets (Mustela putorius furo) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.j. | Other Carnivores (other Carnivora) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 71 | 21 | 0 | 0 | 50 | 12 |
| 1.1. | Pigs (Sus) | 818 | 594 | 61 | 0 | 163 | 41 |
| 1.m. | Goats (Capra) | 44 | 20 | 0 | 0 | 24 | 3 |
| 1.n. | Sheep (Ovis) | 195 | 127 | 20 | 0 | 48 | 34 |
| 1.0. | Cattle (Bos) | 536 | 352 | 16 | 0 | 168 | 9 |
| 1.p. | Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. | New World Monkeys (Ceboidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 56 | 56 | 0 | 0 | 0 | 41 |
| 1.s. | Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. | Other Mammals (other Mammalia) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.u. | Quail (Coturnix coturnix) | 14 | 14 | 0 | 0 | 0 | 0 |
| 1.v. | Other birds (other Aves) | 1011 | 352 | 300 | 0 | 359 | 22 |
| 1.w. | Reptiles (Reptilia) | 40 | 0 | 0 | 0 | 40 | 0 |
| 1.x. | Amphibians (Amphibia) | 865 | 62 | 40 | 0 | 763 | 0 |
| 1.y. | Fish (Pisces) | 1199 | 192 | 4 | 0 | 1003 | 0 |
| 1.z. | TOTAL | 167312 | 47169 | 116991 | 184 | 2968 | 326 |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES
Purpose versus species

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 25313 | 74677 | 20884 | 177 | 2956 | 1296 | 106 | 3225 | 128634 |
| 2.b. | Rats | 5019 | 2949 | 131 | 232 | 3167 | 0 | 422 | 0 | 11920 |
| 2.c. | Guinea-Pigs | 24 | 548 | 1411 | 197 | 967 | 0 | 2 | 0 | 3149 |
| 2.d. | Hamsters | 0 | 117 | 0 | 0 | 0 | 0 | 0 | 0 | 117 |
| 2.e. | Other Rodents | 47 | 0 | 0 | 0 | 0 | 0 | 0 | 60 | 107 |
| 2.f. | Rabbits | 344 | 75 | 17019 | 23 | 928 | 0 | 8 | 42 | 18439 |
| 2.g. | Cats | 0 | 2 | 0 | 0 | 0 | 10 | 0 | 0 | 12 |
| 2.h. | Dogs | 6 | 56 | 0 | 0 | 0 | 0 | 12 | 11 | 85 |
| 2.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.k. | Horses, donkeys and cross breds | 33 | 10 | 0 | 0 | 0 | 22 | 2 | 4 | 71 |
| 2.1. | Pigs | 265 | 255 | 73 | 0 | 0 | 0 | 189 | 36 | 818 |
| 2.m. | Goats | 0 | 4 | 0 | 0 | 0 | 0 | 40 | 0 | 44 |
| 2.n. | Sheep | 20 | 50 | 1 | 42 | 12 | 0 | 70 | 0 | 195 |
| 2.0. | Cattle | 333 | 0 | 0 | 12 | 3 | 0 | 140 | 48 | 536 |
| 2.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.r. | Old World Monkeys | 0 | 56 | 0 | 0 | 0 | 0 | 0 | 0 | 56 |
| 2.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.u. | Quail | 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 14 |
| 2.v. | Other birds | 725 | 151 | 4 | 0 | 0 | 60 | 71 | 0 | 1011 |
| 2.w. | Reptiles | 40 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 40 |
| 2.x. | Amphibians | 860 | 0 | 0 | 0 | 0 | 0 | 5 | 0 | 865 |
| 2.y. | Fish | 876 | 180 | 0 | 0 | 143 | 0 | 0 | 0 | 1199 |
| 2.z. | TOTAL | 33919 | 79130 | 39523 | 683 | 8176 | 1388 | 1067 | 3426 | 167312 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Products versus species

|  | $\begin{gathered} 3.1 \\ \text { Species } \end{gathered}$ | substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 Products/ substances used or intended to be used mainly in the household | Products/ substances used or intended to be used mainly as cosmetics or toiletries | Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 Potential or actual contaminants in the general environment which do not appear in other columns | 3.10 Other toxicological or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 2026 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 930 | 2956 |
| 3.b. | Rats | 1415 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1752 | 3167 |
| 3.c. | Guinea-Pigs | 279 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 688 | 967 |
| 3.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.f. | Rabbits | 715 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 213 | 928 |
| 3.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.h. | Dogs | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.1. | Pigs | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 12 | 12 |
| 3.0. | Cattle | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 |
| 3.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.v. | Other birds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.y. | Fish | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 143 | 143 |
| 3.z. | TOTAL | 4438 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3738 | 8176 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | Species | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 <br> Studies specific to animal diseases | $\begin{gathered} \hline 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 1275 | 3407 | 15919 | 45266 | 95 | 65962 |
| 4.b. | Rats | 506 | 1777 | 609 | 4919 | 0 | 7811 |
| 4.c. | Guinea-Pigs | 0 | 0 | 0 | 905 | 0 | 905 |
| 4.d. | Hamsters | 0 | 0 | 0 | 117 | 0 | 117 |
| 4.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.f. | Rabbits | 53 | 31 | 89 | 294 | 0 | 467 |
| 4.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.h. | Dogs | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.1. | Pigs | 106 | 0 | 0 | 292 | 0 | 398 |
| 4.m. | Goats | 0 | 0 | 0 | 4 | 0 | 4 |
| 4.n. | Sheep | 2 | 0 | 12 | 26 | 0 | 40 |
| 4.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.r. | Old World Monkeys | 0 | 0 | 0 | 56 | 0 | 56 |
| 4.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.v. | Other birds | 54 | 0 | 0 | 6 | 0 | 60 |
| 4.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.x. | Amphibians | 25 | 25 | 0 | 12 | 0 | 62 |
| 4.y. | Fish | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.z. | TOTAL | 2021 | 5240 | 16629 | 51897 | 95 | 75882 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 5.4 <br> Member Country of Council of Europe (but not EC) legislation <br> 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice | 177 | 887 | 0 | 0 | 19909 | 88 | 21061 |
| 5.b. | Rats | 131 | 0 | 0 | 232 | 0 | 0 | 363 |
| 5.c. | Guinea-Pigs | 0 | 636 | 0 | 197 | 775 | 0 | 1608 |
| 5.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.f. | Rabbits | 0 | 12884 | 0 | 32 | 3981 | 145 | 17042 |
| 5.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.h. | Dogs | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.1. | Pigs | 0 | 0 | 0 | 0 | 0 | 73 | 73 |
| 5.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.n. | Sheep | 21 | 22 | 0 | 0 | 0 | 0 | 43 |
| 5.0. | Cattle | 12 | 0 | 0 | 0 | 0 | 0 | 12 |
| 5.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.v. | Other birds | 4 | 0 | 0 | 0 | 0 | 0 | 4 |
| 5.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.y. | Fish | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.z. | TOTAL | 345 | 14429 | 0 | 461 | 24665 | 306 | 40206 |

Examples: 5.2 - France is testing due to a UK (or FR) specific requirement 5.3 - UK is testing according to EC legislation 5.4 - Spain is testing due to a Hungarian requirement 5.5 - Sweden is testing due to a US specific requirement 5.6 - Germany is testing due to a Czech requirement (also an EC

Note: columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.
 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Regulatory requirements versus species


TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2Acute and sub-acute toxicity testing methods <br> (including limit test) |  |  | $\begin{array}{c\|} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{array}$ | 7.4Skinsensitisation | 7.5Eyeirritation | 7.6Sub-chronic andchronictoxicity | 7.7 <br> Carcinogenicity | $7.8$ <br> Developmental toxicity | $\begin{gathered} 7.9 \\ \text { Muta- } \\ \text { genicit } \\ y \end{gathered}$ | 7.10 <br> Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{gathered} \hline 7.12 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 7.13 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | $\begin{aligned} & \hline 7.2 .1 \\ & \text { LD50, } \\ & \text { LC50 } \end{aligned}$ | 7.2.2Other lethal <br> methods | 7.2.3 <br> Non lethal clinical signs methods |  |  |  |  |  |  |  |  |  |  |  |
| 7.a. | Mice | 0 | 293 | 1580 | 0 | 784 | 0 | 0 | 0 | 0 | 154 | 0 | 0 | 145 | 2956 |
| 7.b. | Rats | 0 | 726 | 229 | 104 | 0 | 0 | 1596 | 0 | 0 | 12 | 0 | 0 | 500 | 3167 |
| 7.c. | Guinea-Pigs | 0 | 0 | 119 | 0 | 688 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 160 | 967 |
| 7.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.f. | Rabbits | 0 | 0 | 70 | 123 | 0 | 88 | 0 | 0 | 0 | 0 | 0 | 0 | 647 | 928 |
| 7.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.h. | Dogs | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.1. | Pigs | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 12 | 12 |
| 7.0. | Cattle | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 |
| 7.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.v. | Other birds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.y. | Fish | 0 | 143 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 143 |
| 7.z. | TOTAL | 0 | 1162 | 2001 | 227 | 1472 | 88 | 1596 | 0 | 0 | 166 | 0 | 0 | 1464 | 8176 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products

| $8.1$ <br> Products |  | 8.2Acute and sub-acute toxicity testing <br> methods (including limit test) |  |  | $\begin{gathered} \hline 8.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 8.4 Skin sensitisatio n | $\begin{gathered} 8.5 \\ \text { Eye } \\ \text { irritation } \end{gathered}$ | 8.6 Sub- <br> chronic <br> and <br> chronic <br> toxicity |  | 8.8 <br> Developmental toxicity | 8.9 Muta- genicit $y$ | $8.10$ <br> Reproductive toxicity | 8.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 8.12 \\ & \text { Other } \end{aligned}$ | $\begin{gathered} \hline 8.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 8.a. | Products/substances or devices for human medicine and dentistry and for veterinary medicine | 0 | 381 | 2001 | 62 | 8 | 0 | 662 | 0 | 0 | 6 | 0 | 0 | 1318 | 4438 |
| 8.b. | Products/substances used or intended to be used mainly in agriculture | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8.c. | Products/substances used or intended to be used mainly in industry | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8.d. | Products/substances used or intended to be used mainly in the household | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8.e. | Products/substances used or intended to be used mainly as cosmetics or toiletries | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8.f. | Products/substances used or intended to be used mainly as additives in food for human consumption | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8.g. | Products/substances used or intended to be used mainly as additives in food for animal consumption | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8.h. | Potential or actual contaminants in the general environment which do not appear in other columns | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8.i. | Other toxicological or safety evaluations | 0 | 781 | 0 | 165 | 1464 | 88 | 934 | 0 | 0 | 160 | 0 | 0 | 146 | 3738 |
| 8.j. | TOTAL | 0 | 1162 | 2001 | 227 | 1472 | 88 | 1596 | 0 | 0 | 166 | 0 | 0 | 1464 | 8176 |

## BELGIUM

## Statistical data submitted

The statistical data have been submitted by the "SPF Santé Publique, Sécurité de la Chaine Alimentaire et Environnement" (Federal Public Service of Public Health, Food Chain Safety and Environment).

## Comments of the Belgian authorities

## ANIMALS USED FOR EXPERIMENTAL PURPOSES

## STATISTICS ON USE IN BELGIUM IN 2005

## 1. Laboratories

At the end of 2005, there were 390 approved laboratories in operation which, pursuant to Article 15 of the Royal Decree of 14 November 1993 on the protection of animals used for experimental purposes, provided data on their use of animals for experiments. As in previous years, $25 \%$ of laboratories used no animals.

In 2005, four laboratory approvals were withdrawn at the request of the head of the laboratory because it had ceased operations; five new approvals were issued for laboratories and one for a supplier of animals for experimental purposes.

## 2. Number of animals used in experiments

In all 718976 animals were used. Of the various species used, rodents and rabbits accounted for $92 \%$, fish, reptiles and amphibians accounted for $6 \%$ and birds for $2 \%$ of the total.

Dogs, cats and primates accounted respectively for $0.19 \%, 0.01 \%$ and $0.06 \%$ of the animals used in 2005 (Figure 1: Breakdown of species used in experiments).


Animaux agricoles - agricultural animals; Primates - primates; Autres animaux à sang chaud - other warm-blooded animals; Oiseaux - birds; Animaux à sang froid - cold-blooded animals; Rongeurs rodents; Lapins - rabbits; Chiens/chats - dogs/cats

A comparison of the figures for 2005 with those for previous years (Table 1: Trend in the number of animals used in experiments), shows an increase in the total number of animals of $1.44 \%$ over 2004. That increase was due mainly to greater use of fish ( $+13391,65 \%$ ), birds ( $+2849,26 \%$ ), mice $(+5$ $315,1.1 \%$ ) and, to a lesser extent, dogs ( $+201,27 \%$ ) and ferrets ( $+52,51 \%$ ). There was a substantial drop in the number of monkeys ( $-137,23 \%$ ), rats ( $-12710,11 \%$ ), other rodents ( $-1661,42 \%$ ) and cats ( $-103,56 \%$ ).

Table 1: Trend in the number of animals used in experiments

|  | 2005 | 2004 | 2003 | 2002 | 2001 |
| :---: | :---: | :---: | :---: | :---: | :---: |
| Mice | 488125 | 482810 | 430251 | 460487 | 436266 |
| Rats | 106483 | 119193 | 128284 | 116340 | 112040 |
| Guinea pigs | 39530 | 38781 | 40510 | 34305 | 40204 |
| Hamsters | 1874 | 1688 | 2590 | 2645 | 3163 |
| Other rodents | 2260 | 3921 | 11332 | 16670 | 12693 |
| Rabbits | 21159 | 18577 | 18714 | 10805 | 14631 |
| Total rodents and rabbits | 659431 | 664970 | 631681 | 641252 | 618997 |
| Cats | 81 | 184 | 90 | 100 | 75 |
| Dogs | 1295 | 1014 | 1000 | 1071 | 1036 |
| Ferrets | 154 | 102 | 36 | 20 | 20 |
| Other carnivores | 0 | 0 | 0 | 0 | 0 |
| Total carnivores | 1530 | 1300 | 1126 | 1191 | 1131 |
| Horses, donkeys and cross-breds | 108 | 65 | 93 | 138 | 102 |
| Pigs | 1876 | 2272 | 2637 | 3587 | 4079 |
| Goats | 157 | 125 | 114 | 102 | 217 |
| Sheep | 445 | 495 | 339 | 524 | 492 |
| Cattle | 944 | 982 | 1055 | 1135 | 714 |
| Total ungulates | 3530 | 3939 | 4238 | 5486 | 5604 |
| Prosimians |  | 0 | 0 | 0 | 0 |
| New world monkeys | 0 | 7 | 7 | 20 | 21 |
| Old world monkeys | 449 | 579 | 281 | 547 | 689 |
| Apes | 0 | 0 | 0 | 0 | 0 |
| Total primates | 449 | 586 | 288 | 567 | 710 |
| Other mammals | 59 | 44 | 22 | 8 | 0 |
| Total mammals | 664999 | 670839 | 637355 | 648504 | 626442 |
| Quails | 425 | 350 | 514 | 326 | 134 |
| Other birds | 13266 | 10492 | 12499 | 20026 | 8711 |
| Total birds | 13691 | 10842 | 13013 | 20352 | 8845 |
| Reptiles | 144 | 129 | 30 | 15 | 95 |
| Amphibians | 6177 | 6362 | 1803 | 1601 | 2460 |
| Fish | 33965 | 20574 | 24363 | 24619 | 17375 |
| Total cold-blooded animals | 40286 | 27065 | 26196 | 26235 | 19930 |
| TOTAL ANIMALS | 718976 | 708746 | 676564 | 695.091 | 655.217 |

The following graph (Figure 2: Trend in the number of animals used since 1997) clearly shows that the number of animals used in Belgian laboratories fell between 1997 and 2005 (by 16\%), even though there were some unrepresentative annual fluctuations.


Figure 2: Trend in the number of animals used since 1997

## 3. Experiments carried out

In descending order, animals were used mainly for research and to develop products and devices used in human and veterinary medicine ( $33 \%$ of the animals used), basic research studies ( $29 \%$ ) and tests on the production and quality control of such products and devices (24\%) (Figure 3: Breakdown of the experimental fields). There has been a steady rise in the number of animals used for basic research and the figure in 2005 was the highest ever for this category. As regards production and quality control tests and toxicology tests, $98 \%$ and $90 \%$ respectively of the animals were used to meet legal requirements.


Figure 3: Breakdown of the experimental fields
Diagnostic - diagnostics; Formation -training; Autres - other; Biol. Fond. - basic biology; R\&D - research and development; QC - quality control; Toxicologie - toxicology

The following diagram (Figure 4: Breakdown of experimental fields by the animals most used) shows that, of the animals most used, rats and mice are used mainly for basic research and the development of products and material for medicine ( $65 \%$ ) and for safety tests $(22 \%)$.


Figure 4: Breakdown of experimental fields by the animals most used
Biologie fondamentale - basic biology; R\&D - research and development; QC - quality control; Toxicologie - toxicology; Diagnostic - diagnostics; Formation - training; Autres - other; Lapins rabbits; Animaux à sang froid - cold-blooded animals; Oiseaux - birds; Rongeurs - rodents.

As regards the other species, $92 \%$ of primates and $78 \%$ of dogs were used in toxicology tests for safety.

The use of primates is still linked to the World Health Organisation programme to eradicate poliomyelitis worldwide, a programme for which the bulk of the oral polio vaccine is produced in Belgium. Primates have not been used to produce the vaccine since 2003 and neurovirulence tests on types of vaccine strain are now carried out solely on mice rather then primates, a method which recently became part of international law.

The fields where use has increased significantly since 2004 are training (by 5 166, 71\%), medical diagnosis (by $7475,88 \%$ ) and toxicology tests (by $15026,31 \%$ ).

Toxicology and safety tests account for $9 \%$ of the animals used in experiments in 2005; $90 \%$ of the animals used in toxicology tests were used in safety trials required by laws and regulations (Figure 5: Proportion of quality control and toxicology tests imposed by law).


Figure 5: Proportion of quality control and toxicology tests imposed by law
Obligation légale - legal requirement; Non obligatoire - not compulsory; Qualité Contrôle - quality control; Toxicologie -toxicology.

## 4. Origin of animals used in experiments

The Royal Decree of 14 November 1993 on the protection of animals used for experimental purposes lays down the list of animals which must come from specifically approved suppliers. In $2005,91 \%$ of the animals used in experiments were on that list. Of these, $96 \%$ came from approved suppliers in Belgium, other countries of the European Union and members of the Council of Europe.

Animals belonging to agricultural species and other animals, including cold-blooded animals, do not appear on the list in the Royal Decree of 14 November 1993. They come from suppliers which meet the conditions laid down by the legislation in force for such establishments.


Figure 6: Origin of animals used in experiments
Elevage spécifique - specially bred; Animaux agricoles - agricultural animals; Autres - other; Réutilisés - reused; B+UE+CdE - B+EU+CoE; Utilsiation - use; Origine - origin

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4Animals coming from <br> elsewhere in the EC | 1.5 <br> Animals coming from <br> Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 488125 | 166973 | 298054 | 1079 | 22019 |  |
| 1.b. | Rats (Rattus norvegicus) | 106483 | 19125 | 80233 | 6535 | 590 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 39530 | 5352 | 34178 | 0 | 0 |  |
| 1.d. | Hamsters (Mesocricetus ) | 1874 | 69 | 1773 | 0 | 32 |  |
| 1.e. | Other Rodents (other Rodentia) | 2260 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 21159 | 18347 | 2806 | 0 | 6 | 536 |
| 1.g. | Cats (Felis catus) | 81 | 49 | 32 | 0 | 0 | 78 |
| 1.h. | Dogs (Canis familiaris) | 1295 | 82 | 898 | 23 | 292 | 475 |
| 1.i. | Ferrets (Mustela putorius furo) | 154 | 0 | 154 | 0 | 0 | 0 |
| 1.j. | Other Carnivores (other Carnivora) | 0 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 108 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 1876 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 157 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 445 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 944 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. | New World Monkeys (Ceboidea) | 0 | 0 | 0 | 0 | 0 | 7 |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 449 | 0 | 37 | 0 | 412 | 22 |
| 1.s. | Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. | Other Mammals (other Mammalia) | 59 |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 425 | 421 | 0 | 0 | 4 |  |
| 1.v. | Other birds (other Aves) | 13266 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 144 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 6177 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 33965 |  |  |  |  |  |
| 1.z. | TOTAL | 718976 |  |  |  |  |  |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES
Purpose versus species

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 142620 | 168987 | 114435 | 6487 | 31740 | 15303 | 5518 | 3035 | 488125 |
| 2.b. | Rats | 20078 | 56836 | 13598 | 131 | 12960 | 487 | 1843 | 550 | 106483 |
| 2.c. | Guinea-Pigs | 247 | 5497 | 18039 | 1006 | 14190 | 26 | 525 | 0 | 39530 |
| 2.d. | Hamsters | 131 | 1 | 0 | 1660 | 0 | 0 | 34 | 48 | 1874 |
| 2.e. | Other Rodents | 411 | 1697 | 0 | 0 | 142 | 0 | 0 | 10 | 2260 |
| 2.f. | Rabbits | 1326 | 3888 | 14276 | 329 | 1095 | 0 | 84 | 161 | 21159 |
| 2.g. | Cats | 49 | 0 | 0 | 32 | 0 | 0 | 0 | 0 | 81 |
| 2.h. | Dogs | 115 | 104 | 0 | 38 | 1018 | 7 | 13 | 0 | 1295 |
| 2.i. | Ferrets | 0 | 154 | 0 | 0 | 0 | 0 | 0 | 0 | 154 |
| 2.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.k. | Horses, donkeys and cross breds | 28 | 27 | 15 | 2 | 0 | 1 | 31 | 4 | 108 |
| 2.1. | Pigs | 1197 | 144 | 21 | 187 | 95 | 16 | 113 | 103 | 1876 |
| 2.m. | Goats | 26 | 54 | 0 | 40 | 0 | 0 | 32 | 5 | 157 |
| 2.n. | Sheep | 177 | 123 | 0 | 34 | 24 | 0 | 2 | 85 | 445 |
| 2.0. | Cattle | 97 | 136 | 0 | 484 | 15 | 83 | 17 | 112 | 944 |
| 2.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.r. | Old World Monkeys | 37 | 0 | 0 | 0 | 412 | 0 | 0 | 0 | 449 |
| 2.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.t. | Other Mammals | 28 | 31 | 0 | 0 | 0 | 0 | 0 | 0 | 59 |
| 2.u. | Quail | 421 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 425 |
| 2.v. | Other birds | 11546 | 1269 | 165 | 36 | 238 | 0 | 2 | 10 | 13266 |
| 2.w. | Reptiles | 144 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 144 |
| 2.x. | Amphibians | 5071 | 0 | 0 | 0 | 0 | 30 | 1076 | 0 | 6177 |
| 2.y. | Fish | 25466 | 0 | 0 | 0 | 1769 | 0 | 3130 | 3600 | 33965 |
| 2.z. | TOTAL | 209215 | 238948 | 160549 | 10466 | 63698 | 15953 | 12424 | 7723 | 718976 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Products versus species

|  | $\begin{gathered} 3.1 \\ \text { Species } \end{gathered}$ | substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminents in the general environment which do not appear in other columns | 3.10 Other toxico- logical or $\quad$ safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 30371 | 50 | 50 | 0 | 0 | 0 | 0 | 1254 | 15 | 31740 |
| 3.b. | Rats | 12260 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 700 | 12960 |
| 3.c. | Guinea-Pigs | 14190 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 14190 |
| 3.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 142 | 0 | 142 |
| 3.f. | Rabbits | 1095 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1095 |
| 3.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.h. | Dogs | 1018 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1018 |
| 3.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.1. | Pigs | 80 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 15 | 95 |
| 3.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.n. | Sheep | 24 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 24 |
| 3.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 15 | 15 |
| 3.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.r. | Old World Monkeys | 412 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 412 |
| 3.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.v. | Other birds | 118 | 0 | 0 | 0 | 0 | 0 | 0 | 120 | 0 | 238 |
| 3.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.y. | Fish | 275 | 510 | 0 | 0 | 0 | 0 | 0 | 444 | 540 | 1769 |
| 3.z. | TOTAL | 59843 | 560 | 50 | 0 | 0 | 0 | 0 | 1960 | 1285 | 63698 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 <br> Studies specific to animal diseases | $\begin{gathered} \hline 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 5754 | 62251 | 46356 | 193220 | 9749 | 317330 |
| 4.b. | Rats | 1845 | 29488 | 2602 | 41694 | 119 | 75748 |
| 4.c. | Guinea-Pigs | 233 | 2134 | 0 | 15491 | 5 | 17863 |
| 4.d. | Hamsters | 0 | 0 | 0 | 70 | 0 | 70 |
| 4.e. | Other Rodents | 36 | 585 | 0 | 846 | 198 | 1665 |
| 4.f. | Rabbits | 260 | 5 | 18 | 219 | 321 | 823 |
| 4.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.h. | Dogs | 56 | 16 | 0 | 121 | 2 | 195 |
| 4.i. | Ferrets | 0 | 0 | 0 | 154 | 0 | 154 |
| 4.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 28 | 28 |
| 4.1. | Pigs | 71 | 0 | 0 | 116 | 286 | 473 |
| 4.m. | Goats | 0 | 0 | 0 | 60 | 0 | 60 |
| 4.n. | Sheep | 39 | 0 | 0 | 75 | 0 | 114 |
| 4.0. | Cattle | 4 | 0 | 0 | 0 | 136 | 140 |
| 4.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.r. | Old World Monkeys | 0 | 0 | 0 | 25 | 0 | 25 |
| 4.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.t. | Other Mammals | 6 | 0 | 3 | 25 | 0 | 34 |
| 4.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.v. | Other birds | 0 | 0 | 0 | 211 | 1724 | 1935 |
| 4.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.x. | Amphibians | 9 | 0 | 0 | 3 | 0 | 12 |
| 4.y. | Fish | 0 | 0 | 0 | 0 | 1000 | 1000 |
| 4.z. | TOTAL | 8313 | 94479 | 48979 | 252330 | 13568 | 417669 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 5.4 <br> Member Country of Council of Europe (but not EC) legislation <br> 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice | 0 | 26663 | 0 | 9365 | 83891 | 1003 | 120922 |
| 5.b. | Rats | 0 | 294 | 0 | 1385 | 9621 | 2429 | 13729 |
| 5.c. | Guinea-Pigs | 0 | 2534 | 0 | 4092 | 12410 | 9 | 19045 |
| 5.d. | Hamsters | 0 | 840 | 0 | 0 | 820 | 0 | 1660 |
| 5.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.f. | Rabbits | 0 | 81 | 0 | 219 | 14281 | 24 | 14605 |
| 5.g. | Cats | 0 | 26 | 0 | 0 | 6 | 0 | 32 |
| 5.h. | Dogs | 0 | 22 | 0 | 0 | 16 | 0 | 38 |
| 5.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 2 | 0 | 15 | 17 |
| 5.1. | Pigs | 0 | 82 | 0 | 0 | 105 | 21 | 208 |
| 5.m. | Goats | 0 | 0 | 0 | 0 | 40 | 0 | 40 |
| 5.n. | Sheep | 0 | 2 | 0 | 0 | 32 | 0 | 34 |
| 5.0. | Cattle | 0 | 484 | 0 | 0 | 0 | 0 | 484 |
| 5.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.v. | Other birds | 0 | 201 | 0 | 0 | 0 | 0 | 201 |
| 5.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.y. | Fish | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.z. | TOTAL | 0 | 31229 | 0 | 15063 | 121222 | 3501 | 171015 |

Examples: 5.2 - France is testing due to a UK (or FR) specific requirement 5.3 - UK is testing according to EC legislation 5.4 - Spain is testing due to a Hungarian requirement 5.5 - Sweden is testing due to a US specific requirement 5.6 - Germany is testing due to a Czech requirement (also an EC

Note: columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.
 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Regulatory requirements versus species


TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2Acute and sub-acute toxicity testing methods(including limit test) |  |  | $\begin{array}{c\|} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{array}$ | 7.4Skinsensitisation | 7.5Eyeirritation | 7.6 Subchronic and chronic toxicity | 7.7Carcinogenicity | $7.8$ <br> Developmental toxicity | 7.9Muta-genicit$y$ | 7.10 <br> Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 7.12 \\ & \text { Other } \end{aligned}$ | $\begin{aligned} & \hline 7.13 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | $\begin{aligned} & \hline \text { 7.2.1 } \\ & \text { LD50, } \\ & \text { LC50 } \end{aligned}$ | $\overline{7.2 .2}$ <br> Other lethal methods | 7.2.3 <br> Non lethal clinical signs methods |  |  |  |  |  |  |  |  |  |  |  |
| 7.a. | Mice | 1534 | 15 | 24673 | 0 | 0 | 0 | 1720 | 854 | 457 | 1611 | 100 | 0 | 776 | 31740 |
| 7.b. | Rats | 0 | 60 | 5297 | 0 | 0 | 0 | 1718 | 1604 | 1657 | 531 | 326 | 0 | 1767 | 12960 |
| 7.c. | Guinea-Pigs | 0 | 0 | 14030 | 0 | 160 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 14190 |
| 7.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.e. | Other Rodents | 0 | 142 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 142 |
| 7.f. | Rabbits | 0 | 0 | 169 | 18 | 9 | 12 | 0 | 0 | 814 | 0 | 0 | 0 | 73 | 1095 |
| 7.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.h. | Dogs | 0 | 0 | 474 | 0 | 0 | 0 | 215 | 0 | 0 | 0 | 0 | 0 | 329 | 1018 |
| 7.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.1. | Pigs | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 95 | 95 |
| 7.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 24 | 24 |
| 7.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 15 | 15 |
| 7.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.r. | Old World Monkeys | 0 | 0 | 412 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 412 |
| 7.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.v. | Other birds | 0 | 100 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 138 | 238 |
| 7.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.y. | Fish | 1298 | 0 | 0 | 0 | 0 | 0 | 76 | 0 | 0 | 0 | 0 | 0 | 395 | 1769 |
| 7.z. | TOTAL | 2832 | 317 | 45055 | 18 | 169 | 12 | 3729 | 2458 | 2928 | 2142 | 426 | 0 | 3612 | 63698 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products


## CYPRUS

## Statistical data submitted

The statistical data have been submitted by "Veterinary Services of the Republic of Cyprus".
Remark: data are reported in table 1, 2 and 4 only.

## Comments of the Cyprus authorities

The Director of the Veterinary Services of the Republic of Cyprus is empowered by Law to regulate all activities that relate to the use of experimental animals. At present, within the areas under the control of the Republic, only rodents (mice) are used in animal experimentation. These primarily include genetic models for various diseases or processes with main emphasis on Central Nervous System complications and development.

These activities began to take place in Cyprus in March 2003 and are all carried out in one research establishment, the Cyprus Institute of Neurology and Genetics (www.cing.ac.cy).

The Veterinary Services are satisfied that the animals are kept in a very rigorously monitored, pathogen-free environment (monitored according to FELASA guidelines). No outbreak of all pathogens tested has been observed. We are also satisfied that the principles of the three Rs are duly adhered to.

Dr. Giorgos Neophytou
Director of Veterinary Services

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

| $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 <br> Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | $\begin{gathered} 1.6 \\ \begin{array}{c} \text { Animals coming from } \\ \text { other origins } \end{array} \end{gathered}$ | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. Mice (Mus musculus) | 967 | 930 | 12 |  | 25 |  |
| 1.b. Rats (Rattus norvegicus) | 0 |  |  |  |  |  |
| 1.c. Guinea-Pigs (Cavia porcellus) | 0 |  |  |  |  |  |
| 1.d. Hamsters (Mesocricetus ) | 0 |  |  |  |  |  |
| 1.e. Other Rodents (other Rodentia) |  |  |  |  |  |  |
| 1.f. Rabbits (Oryctolagus cuniculus) | 0 |  |  |  |  |  |
| 1.g. Cats (Felis catus) | 0 |  |  |  |  |  |
| 1.h. Dogs (Canis familiaris) | 0 |  |  |  |  |  |
| 1.i. Ferrets (Mustela putorius furo) | 0 |  |  |  |  |  |
| 1.j. Other Carnivores (other Carnivora) |  |  |  |  |  |  |
| 1.k. Horses, donkeys and cross breds (Equidae) |  |  |  |  |  |  |
| 1.1. Pigs (Sus) |  |  |  |  |  |  |
| 1.m. Goats (Capra) |  |  |  |  |  |  |
| 1.n. Sheep (Ovis) |  |  |  |  |  |  |
| 1.0. Cattle (Bos) |  |  |  |  |  |  |
| 1.p. Prosimians (Prosimia) | 0 |  |  |  |  |  |
| 1.q. New World Monkeys (Ceboidea) | 0 |  |  |  |  |  |
| 1.r. Old World Monkeys (Cercopithecoidea) | 0 |  |  |  |  |  |
| 1.s. Apes (Hominoidea) | 0 |  |  |  |  |  |
| 1.t. Other Mammals (other Mammalia) |  |  |  |  |  |  |
| 1.u. Quail (Coturnix coturnix) | 0 |  |  |  |  |  |
| 1.v. Other birds (other Aves) |  |  |  |  |  |  |
| 1.w. Reptiles (Reptilia) |  |  |  |  |  |  |
| 1.x. Amphibians (Amphibia) |  |  |  |  |  |  |
| 1.y. Fish (Pisces) |  |  |  |  |  |  |
| 1.z. TOTAL | 967 |  |  |  |  |  |

 updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES
Purpose versus species

|  | $\begin{gathered} \hline 2.1 \\ \text { Species } \end{gathered}$ | 2.2 Biologic al studies of a fundame ntal nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) |  |  | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8 <br> Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 822 |  |  |  |  |  | 145 |  | 967 |
| 2.b. | Rats |  |  |  |  |  |  |  |  | 0 |
| 2.c. | Guinea-Pigs |  |  |  |  |  |  |  |  | 0 |
| 2.d. | Hamsters |  |  |  |  |  |  |  |  | 0 |
| 2.e. | Other Rodents |  |  |  |  |  |  |  |  | 0 |
| 2.f. | Rabbits |  |  |  |  |  |  |  |  | 0 |
| 2.g. | Cats |  |  |  |  |  |  |  |  | 0 |
| 2.h. | Dogs |  |  |  |  |  |  |  |  | 0 |
| 2.i. | Ferrets |  |  |  |  |  |  |  |  | 0 |
| 2.j. | Other Carnivores |  |  |  |  |  |  |  |  | 0 |
| 2.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  | 0 |
| 2.1. | Pigs |  |  |  |  |  |  |  |  | 0 |
| 2.m. | Goats |  |  |  |  |  |  |  |  | 0 |
| 2.n. | Sheep |  |  |  |  |  |  |  |  | 0 |
| 2.0. | Cattle |  |  |  |  |  |  |  |  | 0 |
| 2.p. | Prosimians |  |  |  |  |  |  |  |  | 0 |
| 2.q. | New World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.r. | Old World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.s. | Apes |  |  |  |  |  |  |  |  | 0 |
| 2.t. | Other Mammals |  |  |  |  |  |  |  |  | 0 |
| 2.u. | Quail |  |  |  |  |  |  |  |  | 0 |
| 2.v. | Other birds |  |  |  |  |  |  |  |  | 0 |
| 2.w. | Reptiles |  |  |  |  |  |  |  |  | 0 |
| 2.x. | Amphibians |  |  |  |  |  |  |  |  | 0 |
| 2.y. | Fish |  |  |  |  |  |  |  |  | 0 |
| 2.z. | TOTAL | 822 | 0 | 0 | 0 | 0 | 0 | 145 | 0 | 967 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES


## CZECH REPUBLIC

## Statistical data submitted

The statistical data have been submitted by the "Central Commission for Animal Welfare (Ústřední komise pro ochranu zvírat)".

## Comments of the Czech authorities

## National comments for the preparation of the 5th Statistical report on the use of experimental animals - Czech Republic

Protection of animals and animal welfare in the Czech Republic is the responsibility of the Ministry of Agriculture, which provides the organisation background necessary for the activities performed by the Central Commission for Animal Welfare (Ústředni komise pro ochranu zvířat). The animal welfare activities are implemented pursuant to Act No. 246/1992 Coll., on the protection of animals against cruelty, as amended. The supervision over these matters has been the responsibility of the Regional Veterinary Administrations' inspectors in 13 regions of the Czech Republic and the Municipal Veterinary Administration in Prague.

There were 93 inspections conducted in laboratory animal breeding establishments involving 120067 animals, corrective measures were imposed in 3 cases and administrative procedure was initiated twice.

In 2005 a total of 330933 animals were used for experimental and other scientific purposes in the CR. It shall be pointed out that $36.99 \%$ of it is represented by ringed birds (122 422 birds) since pursuant to the relevant Czech legislation even bird ringing is an experiment.

Of the remaining 208511 animals used for experimental and scientific purposes only $0.01 \%$ were cats ( 29 cats), $0.13 \%$ dogs ( 264 dogs), $0.02 \%$ monkeys ( 51 monkeys), while no apes were used. Rodents and rabbits ( 62.16 \%, i.e. 129615 animals) and fish ( $33.29 \%$, i.e. 69418 fish) represent the prevailing majority of animals used.

In the last couple of years the number of experimental animals used in the CR was approximately the same (approximately 220000 animals excluding ringed birds). Fluctuations in numbers, if any, are caused by experiments using fish and poultry because these experiments are usually conducted on a large group of animals (a flock in houses or stock in water reservoirs).

The use of alternative methods to experiments on animals has been pushed through in the CR. Persons who manage, control and conduct experiments on animals are obliged to seek in the registers of validated alternative methods such methods which are applicable to their experiment. In the experimental project the applicant shall declare in writing that no validated alternative method can be applied for the given purpose.

The training courses for persons who manage, control and conduct experiments on animals comprise also teaching of alternative methods to experiments on animals.

Doc. MVDr. Richard S O V J Á K, CSc.
Chairman

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6 Animals coming from other origins | $\begin{gathered} 1.7 \\ \text { Re-used animals } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 82252 | 75473 | 4708 | 2071 |  |  |
| 1.b. | Rats (Rattus norvegicus) | 31703 | 29924 | 1087 | 240 | 452 |  |
|  | Guinea-Pigs (Cavia porcellus) | 4075 | 4075 |  |  |  |  |
| 1.d. | Hamsters (Mesocricetus ) | 220 | 220 |  |  |  |  |
| 1.e. | Other Rodents (other Rodentia) | 5798 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 5567 | 5567 |  |  |  | 119 |
| 1.g. | Cats (Felis catus) | 29 | 3 |  |  | 26 |  |
| 1.h. | Dogs (Canis familiaris) | 264 | 264 |  |  |  | 24 |
| 1.i. | Ferrets (Mustela putorius furo) | 159 | 159 |  |  |  |  |
| 1.j. | Other Carnivores (other Carnivora) | 7 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 314 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 1392 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 56 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 720 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 711 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 |  |  |  |  |  |
| 1.q. | New World Monkeys (Ceboidea) | 0 |  |  |  |  |  |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 51 | 51 |  |  |  | 30 |
| 1.s. | Apes (Hominoidea) | 0 |  |  |  |  |  |
| 1.t. | Other Mammals (other Mammalia) | 188 |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 30 | 30 |  |  |  |  |
| 1.v. | Other birds (other Aves) | 126211 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 1475 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 293 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 69418 |  |  |  |  |  |
| 1.z. | TOTAL | 330933 |  |  |  |  |  |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES
Purpose versus species

|  | $\begin{gathered} \hline 2.1 \\ \text { Species } \end{gathered}$ | 2.2 Biologic al studies of a fundame ntal nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 <br> Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8 <br> Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 33319 | 4698 | 8962 | 14401 | 2673 | 9320 | 3338 | 5541 | 82252 |
| 2.b. | Rats | 25532 | 2462 | 146 | 920 | 911 | 77 | 1655 |  | 31703 |
| 2.c. | Guinea-Pigs | 433 | 4 | 1575 | 1048 | 527 | 457 | 31 |  | 4075 |
| 2.d. | Hamsters | 115 |  | 55 | 40 |  | 10 |  |  | 220 |
| 2.e. | Other Rodents | 5449 |  |  | 187 |  |  | 162 |  | 5798 |
| 2.f. | Rabbits | 352 | 16 | 1351 | 2962 | 448 | 344 | 83 | 11 | 5567 |
| 2.g. | Cats | 3 |  |  | 26 |  |  |  |  | 29 |
| 2.h. | Dogs | 4 |  | 10 | 100 | 145 | 5 |  |  | 264 |
| 2.i. | Ferrets |  | 126 | 7 |  |  | 6 | 20 |  | 159 |
| 2.j. | Other Carnivores | 7 |  |  |  |  |  |  |  | 7 |
| 2.k. | Horses, donkeys and cross breds |  |  |  | 208 |  |  | 100 | 6 | 314 |
| 2.1. | Pigs | 502 |  |  | 569 |  | 85 | 236 |  | 1392 |
| 2.m. | Goats | 56 |  |  |  |  |  |  |  | 56 |
| 2.n. | Sheep | 83 |  |  | 51 |  |  | 19 | 567 | 720 |
| 2.0. | Cattle | 152 | 241 |  | 40 |  | 12 | 84 | 182 | 711 |
| 2.p. | Prosimians |  |  |  |  |  |  |  |  | 0 |
| 2.q. | New World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.r. | Old World Monkeys |  |  |  |  | 51 |  |  |  | 51 |
| 2.s. | Apes |  |  |  |  |  |  |  |  | 0 |
| 2.t. | Other Mammals | 188 |  |  |  |  |  |  |  | 188 |
| 2.u. | Quail |  |  |  |  | 30 |  |  |  | 30 |
| 2.v. | Other birds | 122422 |  | 42 | 2556 |  | 6 | 585 | 600 | 126211 |
| 2.w. | Reptiles | 755 |  |  |  |  |  | 720 |  | 1475 |
| 2.x. | Amphibians | 208 |  |  |  |  |  | 85 |  | 293 |
| 2.y. | Fish | 26935 |  |  | 1422 | 26693 | 870 | 11866 | 1632 | 69418 |
| 2.z. | TOTAL | 216515 | 7547 | 12148 | 24530 | 31478 | 11192 | 18984 | 8539 | 330933 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Products versus species

|  | $\begin{gathered} 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminents in the general environment which do not appear in other columns | 3.10 <br> Other toxicological or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 2300 |  | 68 |  |  |  | 600 | 405 |  | 3373 |
| 3.b. | Rats | 663 |  | 248 |  |  |  | 150 | 200 |  | 1261 |
| 3.c. | Guinea-Pigs | 30 | 26 | 471 |  |  |  |  |  |  | 527 |
| 3.d. | Hamsters |  |  |  |  |  |  |  |  |  | 0 |
| 3.e. | Other Rodents |  |  |  |  |  |  |  |  |  | 0 |
| 3.f. | Rabbits | 245 | 4 | 174 |  |  |  |  | 25 |  | 448 |
| 3.g. | Cats |  |  |  |  |  |  |  |  |  | 0 |
| 3.h. | Dogs | 145 |  |  |  |  |  |  |  |  | 145 |
| 3.i. | Ferrets |  |  |  |  |  |  |  |  |  | 0 |
| 3.j. | Other Carnivores |  |  |  |  |  |  |  |  |  | 0 |
| 3.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  | 0 |
| 3.1. | Pigs |  |  |  |  |  |  |  |  |  | 0 |
| 3.m. | Goats |  |  |  |  |  |  |  |  |  | 0 |
| 3.n. | Sheep |  |  |  |  |  |  |  |  |  | 0 |
| 3.0. | Cattle |  |  |  |  |  |  |  |  |  | 0 |
| 3.p. | Prosimians |  |  |  |  |  |  |  |  |  | 0 |
| 3.q. | New World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.r. | Old World Monkeys | 51 |  |  |  |  |  |  |  |  | 51 |
| 3.s. | Apes |  |  |  |  |  |  |  |  |  | 0 |
| 3.t. | Other Mammals |  |  |  |  |  |  |  |  |  | 0 |
| 3.u. | Quail |  |  |  |  |  |  |  | 25 |  | 25 |
| 3.v. | Other birds |  |  |  |  |  |  |  |  |  | 0 |
| 3.w. | Reptiles |  |  |  |  |  |  |  |  |  | 0 |
| 3.x. | Amphibians |  |  |  |  |  |  |  |  |  | 0 |
| 3.y. | Fish | 1468 | 90 | 2676 |  |  |  |  | 19523 | 1891 | 25648 |
| 3.z. | TOTAL | 4902 | 120 | 3637 | 0 | 0 | 0 | 750 | 20178 | 1891 | 31478 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  |  | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 <br> Studies specific to animal diseases | $\begin{gathered} 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 1473 | 1230 | 9036 | 15146 | 4672 | 31557 |
| 4.b. | Rats | 5697 | 2896 | 694 | 6104 | 136 | 15527 |
| 4.c. | Guinea-Pigs | 10 |  |  | 13 | 6 | 29 |
| 4.d. | Hamsters |  |  |  | 10 | 20 | 30 |
| 4.e. | Other Rodents |  |  |  |  | 361 | 361 |
| 4.f. | Rabbits | 167 |  | 3 | 161 | 72 | 403 |
| 4.g. | Cats | 3 |  |  |  |  | 3 |
| 4.h. | Dogs | 2 |  |  |  |  | 2 |
| 4.i. | Ferrets | 126 |  |  | 6 |  | 132 |
| 4.j. | Other Carnivores |  |  |  |  |  | 0 |
| 4.k. | Horses, donkeys and cross breds |  |  |  |  |  | 0 |
| 4.1. | Pigs | 31 |  | 30 | 188 | 40 | 289 |
| 4.m. | Goats |  |  |  |  | 56 | 56 |
| 4.n. | Sheep | 29 |  |  |  | 28 | 57 |
| 4.0. | Cattle |  |  |  |  | 17 | 17 |
| 4.p. | Prosimians |  |  |  |  |  | 0 |
| 4.q. | New World Monkeys |  |  |  |  |  | 0 |
| 4.r. | Old World Monkeys |  |  |  |  |  | 0 |
| 4.s. | Apes |  |  |  |  |  | 0 |
| 4.t. | Other Mammals |  |  |  |  |  | 0 |
| 4.u. | Quail |  |  |  | 5 |  | 5 |
| 4.v. | Other birds |  |  |  | 111 | 1093 | 1204 |
| 4.w. | Reptiles |  |  |  |  |  | 0 |
| 4.x. | Amphibians |  |  |  |  |  | 0 |
| 4.y. | Fish |  |  |  |  | 1430 | 1430 |
| 4.z. | TOTAL | 7538 | 4126 | 9763 | 21744 | 7931 | 51102 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 <br> National legislation specific to a single EC Member State <br> 1) | 6.3 EC legislation including European Pharmacopoeia (requirements) | 6.4 <br> Member Country of Council of Europe (but not EC) legislation <br> 2) | 6.5 Other legislation | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | 6.7 No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice | 278 | 2170 |  |  |  | 225 | 2673 |
| 6.b. | Rats | 224 | 663 | 24 |  |  |  | 911 |
|  | Guinea-Pigs | 351 | 106 | 70 |  |  |  | 527 |
| 6.d. | Hamsters |  |  |  |  |  |  | 0 |
| 6.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 6.f. | Rabbits | 182 | 257 | 9 |  |  |  | 448 |
| 6.g. | Cats |  |  |  |  |  |  | 0 |
| 6.h. | Dogs |  | 145 |  |  |  |  | 145 |
| 6.i. | Ferrets |  |  |  |  |  |  | 0 |
| 6.j. | Other Carnivores |  |  |  |  |  |  | 0 |
|  | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 6.1. | Pigs |  |  |  |  |  |  | 0 |
| 6.m. | Goats |  |  |  |  |  |  | 0 |
| 6.n. | Sheep |  |  |  |  |  |  | 0 |
| 6.0. | Cattle |  |  |  |  |  |  | 0 |
| 6.p. | Prosimians |  |  |  |  |  |  | 0 |
|  | New World Monkeys |  |  |  |  |  |  | 0 |
|  | Old World Monkeys |  | 51 |  |  |  |  | 51 |
|  | Apes |  |  |  |  |  |  | 0 |
|  | Other Mammals |  |  |  |  |  |  | 0 |
| 6.u. | Quail |  |  |  |  |  | 25 | 25 |
| 6.v. | Other birds |  |  |  |  |  |  | 0 |
| 6.w. | Reptiles |  |  |  |  |  |  | 0 |
|  | Amphibians |  |  |  |  |  |  | 0 |
| 6.y. | Fish | 6476 | 15055 | 312 |  |  | 4855 | 26698 |
| 6.z. | TOTAL | 7511 | 18447 | 415 |  | 0 | 5105 | 31478 |
| Examples: 6.2 - France is testing due to a UK (or FR) specific requirement <br>  6.3 - UK is testing according to EC legislation <br>  6.4 - Spain is testing due to a Hungarian requirement <br>  6.5 - Sweden is testing due to a US specific requirement <br>  6.6 - Germany is testing due to a Czech requirement (also an EC |  |  |  | Example: a test required by French legisla ISO protocol must be coded as a entered into column 6.2 in the ta |  | imposing that the tes tual test method, guid d carried out in Belgi al (FR) legislative req bmitted by Belgium. | carried out and or protocol. ccording to an nent and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2Acute and sub-acute toxicity testing methods <br> (including limit test) |  |  | $\begin{array}{c\|} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{array}$ | 7.4 Skin sensitisatio n | 7.5 Eye irritation | 7.6 Sub- chronic and chronic toxicity | $7.7$ <br> Carcinogenicity | 7.8 Developmental toxicity | 7.9 Muta- genicit $y$ | 7.10 Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 7.12 \\ & \text { Other } \end{aligned}$ | $7.13$ <br> Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 1055 |  |  |  | 68 |  | 1115 |  | 120 |  | 90 |  | 225 | 2673 |
| 7.b. | Rats | 298 |  |  |  |  |  | 613 |  |  |  |  |  |  | 911 |
| 7.c. | Guinea-Pigs |  |  |  | 40 | 487 |  |  |  |  |  |  |  |  | 527 |
| 7.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.e. | Other Rodents |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.f. | Rabbits |  |  |  | 259 |  | 164 |  |  |  | 25 |  |  |  | 448 |
| 7.g. | Cats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.h. | Dogs |  |  |  |  |  |  | 145 |  |  |  |  |  |  | 145 |
| 7.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.1. | Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.m. | Goats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.n. | Sheep |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.0. | Cattle |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.r. | Old World Monkeys |  |  |  |  |  |  | 51 |  |  |  |  |  |  | 51 |
| 7.s. | Apes |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.u. | Quail |  |  | 25 |  |  |  |  |  |  |  |  |  |  | 25 |
| 7.v. | Other birds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.y. | Fish | 22501 |  |  |  |  |  | 155 |  |  |  | 1600 | 2442 |  | 26698 |
| 7.z. | TOTAL | 23854 | 0 | 25 | 299 | 555 | 164 | 2079 | 0 | 120 | 25 | 1690 | 2442 | 225 | 31478 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products


## DENMARK

## Statistical data submitted

The statistical data have been submitted by the "Dyreforsøgstilsynet" (Animal Experiments Inspectorate).

## Comments of Danish authorities

None

## TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

## Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 208375 | 109300 | 96573 | 0 | 2502 | 145 |
| 1.b. | Rats (Rattus norvegicus) | 85664 | 45960 | 37649 | 725 | 1330 | 71 |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 5046 | 1204 | 3838 | 0 | 4 | 2 |
| 1.d. | Hamsters (Mesocricetus ) | 402 | 402 | 0 | 0 | 0 | 0 |
| 1.e. | Other Rodents (other Rodentia) | 6381 | 0 | 0 | 0 | 0 | 0 |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 5805 | 4288 | 1359 | 18 | 140 | 739 |
| 1.g. | Cats (Felis catus) | 16 | 4 | 0 | 4 | 8 | 0 |
| 1.h. | Dogs (Canis familiaris) | 566 | 10 | 514 | 0 | 42 | 84 |
| 1.i. | Ferrets (Mustela putorius furo) | 19 | 0 | 0 | 0 | 19 | 0 |
| 1.j. | Other Carnivores (other Carnivora) | 242 | 0 | 0 | 0 | 0 | 0 |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 62 | 0 | 0 | 0 | 0 | 0 |
| 1.1. | Pigs (Sus) | 7697 | 0 | 0 | 0 | 0 | 0 |
| 1.m. | Goats (Capra) | 199 | 0 | 0 | 0 | 0 | 0 |
| 1.n. | Sheep (Ovis) | 156 | 0 | 0 | 0 | 0 | 0 |
| 1.0. | Cattle (Bos) | 489 | 0 | 0 | 0 | 0 | 0 |
| 1.p. | Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. | New World Monkeys (Ceboidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.s. | Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. | Other Mammals (other Mammalia) | 185 | 0 | 0 | 0 | 0 | 0 |
| 1.u. | Quail (Coturnix coturnix) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.v. | Other birds (other Aves) | 7784 | 0 | 0 | 0 | 0 | 0 |
| 1.w. | Reptiles (Reptilia) | 54 | 0 | 0 | 0 | 0 | 0 |
| 1.x. | Amphibians (Amphibia) | 840 | 0 | 0 | 0 | 0 | 0 |
| 1.y. | Fish (Pisces) | 35958 | 0 | 0 | 0 | 0 | 0 |
| 1.z. | TOTAL | 365940 | 0 | 0 | 0 | 0 | 0 |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

## Purpose versus species

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6 ) | 2.4 <br> Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7Diagnosis of <br> disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 50339 | 128153 | 13842 | 165 | 3742 | 2524 | 1441 | 8169 | 208375 |
| 2.b. | Rats | 18795 | 54087 | 860 | 0 | 8786 | 703 | 1984 | 449 | 85664 |
| 2.c. | Guinea-Pigs | 393 | 850 | 1434 | 0 | 2303 | 66 | 0 | 0 | 5046 |
| 2.d. | Hamsters | 338 | 0 | 0 | 0 | 64 | 0 | 0 | 0 | 402 |
| 2.e. | Other Rodents | 0 | 6343 | 0 | 0 | 0 | 38 | 0 | 0 | 6381 |
| 2.f. | Rabbits | 247 | 700 | 882 | 82 | 556 | 3232 | 104 | 2 | 5805 |
| 2.g. | Cats | 12 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 16 |
| 2.h. | Dogs | 46 | 109 | 0 | 0 | 407 | 0 | 4 | 0 | 566 |
| 2.i. | Ferrets | 19 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 19 |
| 2.j. | Other Carnivores | 242 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 242 |
| 2.k. | Horses, donkeys and cross breds | 39 | 0 | 12 | 0 | 0 | 0 | 11 | 0 | 62 |
| 2.1. | Pigs | 3992 | 1807 | 20 | 29 | 581 | 483 | 350 | 435 | 7697 |
| 2.m. | Goats | 26 | 3 | 0 | 0 | 0 | 163 | 1 | 6 | 199 |
| 2.n. | Sheep | 125 | 27 | 4 | 0 | 0 | 0 | 0 | 0 | 156 |
| 2.0. | Cattle | 444 | 30 | 0 | 2 | 0 | 0 | 13 | 0 | 489 |
| 2.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.t. | Other Mammals | 137 | 48 | 0 | 0 | 0 | 0 | 0 | 0 | 185 |
| 2.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.v. | Other birds | 2695 | 0 | 2 | 0 | 0 | 5087 | 0 | 0 | 7784 |
| 2.w. | Reptiles | 54 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 54 |
| 2.x. | Amphibians | 597 | 93 | 0 | 0 | 0 | 0 | 150 | 0 | 840 |
| 2.y. | Fish | 10284 | 23710 | 0 | 0 | 1480 | 0 | 84 | 400 | 35958 |
| 2.z. | TOTAL | 88824 | 215960 | 17056 | 278 | 17919 | 12296 | 4146 | 9461 | 365940 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Products versus species

|  | $\begin{gathered} 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminents in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 2733 | 0 | 556 | 51 | 0 | 0 | 0 | 25 | 377 | 3742 |
| 3.b. | Rats | 5453 | 2138 | 355 | 134 | 0 | 33 | 0 | 561 | 112 | 8786 |
| 3.c. | Guinea-Pigs | 2102 | 0 | 45 | 0 | 0 | 0 | 0 | 156 | 0 | 2303 |
| 3.d. | Hamsters | 64 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 64 |
| 3.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.f. | Rabbits | 407 | 0 | 9 | 0 | 0 | 135 | 0 | 0 | 5 | 556 |
| 3.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.h. | Dogs | 407 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 407 |
| 3.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.1. | Pigs | 581 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 581 |
| 3.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.v. | Other birds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.y. | Fish | 0 | 0 | 1080 | 0 | 0 | 0 | 0 | 400 | 0 | 1480 |
| 3.z. | TOTAL | 11747 | 2138 | 2045 | 185 | 0 | 168 | 0 | 1142 | 494 | 17919 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 Studies specific to animal diseases | $\begin{gathered} 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 1902 | 92293 | 20255 | 30999 | 716 | 146165 |
| 4.b. | Rats | 3072 | 35360 | 332 | 27760 | 96 | 66620 |
| 4.c. | Guinea-Pigs | 65 | 629 | 0 | 281 | 24 | 999 |
| 4.d. | Hamsters | 171 | 0 | 0 | 0 | 0 | 171 |
| 4.e. | Other Rodents | 0 | 5923 | 0 | 420 | 0 | 6343 |
| 4.f. | Rabbits | 142 | 8 | 0 | 740 | 2 | 892 |
| 4.g. | Cats | 0 | 12 | 0 | 0 | 0 | 12 |
| 4.h. | Dogs | 0 | 17 | 0 | 92 | 42 | 151 |
| 4.i. | Ferrets | 0 | 19 | 0 | 0 | 0 | 19 |
| 4.j. | Other Carnivores | 0 | 0 | 0 | 0 | 102 | 102 |
| 4.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 26 | 26 |
| 4.1. | Pigs | 254 | 172 | 0 | 1616 | 665 | 2707 |
| 4.m. | Goats | 0 | 0 | 0 | 29 | 0 | 29 |
| 4.n. | Sheep | 0 | 0 | 0 | 50 | 0 | 50 |
| 4.0. | Cattle | 0 | 0 | 0 | 0 | 10 | 10 |
| 4.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.v. | Other birds | 0 | 0 | 0 | 0 | 3714 | 3714 |
| 4.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.x. | Amphibians | 0 | 127 | 0 | 0 | 0 | 127 |
| 4.y. | Fish | 0 | 0 | 0 | 0 | 2800 | 2800 |
| 4.z. | TOTAL | 5606 | 134560 | 20587 | 61987 | 8197 | 230937 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 EC legislation including European Pharmacopoeia (requirements) | 5.4 Member Country of Council of Europe (but not EC) legislation 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice | 86 | 517 | 0 | 0 | 12882 | 522 | 14007 |
| 5.b. | Rats | 96 | 0 | 0 | 0 | 764 | 0 | 860 |
| 5.c. | Guinea-Pigs | 0 | 0 | 0 | 0 | 1332 | 102 | 1434 |
| 5.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.f. | Rabbits | 7 | 0 | 0 | 30 | 397 | 530 | 964 |
| 5.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.h. | Dogs | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 12 | 12 |
| 5.1. | Pigs | 25 | 0 | 0 | 0 | 24 | 0 | 49 |
| 5.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 4 | 4 |
| 5.0. | Cattle | 0 | 0 | 0 | 0 | 2 | 0 | 2 |
| 5.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.v. | Other birds | 0 | 0 | 0 | 2 | 0 | 0 | 2 |
| 5.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.y. | Fish | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.z. | TOTAL | 214 | 517 | 0 | 32 | 15401 | 1170 | 17334 |

Examples:
5.2 - France is testing due to a UK (or FR) specific requirement 5.3-UK is testing according to EC legislation 5.4 - Spain is testing due to a Hungarian requirement 5.5 - Sweden is testing due to a US specific requirement 5.6 - Germany is testing due to a Czech requirement (also an EC

Note:
Example:
columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

## TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 National legislation specific to a single EC Member State 1) | 6.3 EC legislation including European Pharmacopoeia (requirements) | 6.4 Member Country of Council of Europe (but not EC) legislation 2) | 6.5 Other legislation | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | 6.7 No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice | 223 | 0 | 0 | 0 | 2190 | 1329 | 3742 |
| 6.b. | Rats | 0 | 0 | 0 | 0 | 5850 | 2936 | 8786 |
| 6.c. | Guinea-Pigs | 0 | 0 | 0 | 0 | 2112 | 191 | 2303 |
| 6.d. | Hamsters | 0 | 0 | 0 | 0 | 64 | 0 | 64 |
| 6.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.f. | Rabbits | 0 | 0 | 0 | 0 | 416 | 140 | 556 |
| 6.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.h. | Dogs | 0 | 0 | 0 | 0 | 407 | 0 | 407 |
| 6.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.1. | Pigs | 0 | 0 | 0 | 0 | 581 | 0 | 581 |
| 6.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.v. | Other birds | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.y. | Fish | 0 | 0 | 0 | 1080 | 0 | 400 | 1480 |
| 6.z. | TOTAL | 223 | 0 | 0 | 1080 | 11620 | 4996 | 17919 |

Examples: $\quad 6.2$ - France is testing due to a UK (or FR) specific requirement 6.3-UK is testing according to EC legislation 6.4 - Spain is testing due to a Hungarian requirement 6.5 - Sweden is testing due to a US specific requirement 6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note: $\quad$ columns 6.2-6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

|  | $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ | Acute and |  | sting methods <br> t) <br> 7.2.3 <br> Non lethal clinical signs methods | $\begin{gathered} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 7.4 Skin sensitisatio n | 7.5 Eye irritation | 7.6 Sub- chronic and chronic toxicity | $7.7$ <br> Carcinogenicity | 7.8 <br> Developmental toxicity | $\begin{gathered} 7.9 \\ \text { Muta- } \\ \text { genicit } \\ y \end{gathered}$ | 7.10 Reproductive toxicity | 7.11 Toxicity to aquatic vertebrates not included in other columns | $\begin{gathered} \hline 7.12 \\ \text { Other } \end{gathered}$ | $\begin{gathered} \hline 7.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 0 | 0 | 2363 | 0 | 30 | 0 | 216 | 0 | 0 | 325 | 14 | 0 | 794 | 3742 |
| 7.b. | Rats | 0 | 0 | 1244 | 0 | 0 | 0 | 4585 | 3 | 116 | 0 | 2612 | 0 | 226 | 8786 |
| 7.c. | Guinea-Pigs | 0 | 0 | 1177 | 0 | 801 | 0 | 169 | 0 | 0 | 0 | 0 | 0 | 156 | 2303 |
| 7.d. | Hamsters | 0 | 0 | 28 | 0 | 0 | 0 | 36 | 0 | 0 | 0 | 0 | 0 | 0 | 64 |
| 7.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.f. | Rabbits | 0 | 0 | 0 | 53 | 0 | 5 | 294 | 0 | 0 | 0 | 0 | 0 | 204 | 556 |
| 7.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.h. | Dogs | 0 | 0 | 20 | 0 | 0 | 0 | 381 | 0 | 0 | 0 | 0 | 0 | 6 | 407 |
| 7.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.1. | Pigs | 0 | 0 | 0 | 8 | 0 | 0 | 473 | 0 | 0 | 0 | 100 | 0 | 0 | 581 |
| 7.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.v. | Other birds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.y. | Fish | 1080 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 400 | 0 | 1480 |
| 7.z. | TOTAL | 1080 | 0 | 4832 | 61 | 831 | 5 | 6154 | 3 | 116 | 325 | 2726 | 400 | 1386 | 17919 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products


## GERMANY

## Statistical data submitted

The statistical data have been submitted by the "Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft" (Federal Ministry for Consumer protection, Food and Agriculture).

## Comments of German authorities

Further to the German Government's communications of 27 July 2006 regarding statistical information on the use of animals for experimental purposes, I now inform you of the following:

The German Government seeks to reduce animal experiments and to support the development of alternative methods (point 8.6 paragraph 3 of the 11 November 2005 coalition agreement). For example, the volume of assistance for the support priority "methods to replace animal experiments" has been increased from $€ 3.4$ million in 2005 to $€ 4$ million in 2006 - an increase of almost $18 \%$. Furthermore, for many years the Federal Ministry of Food, Agriculture and Consumer Protection has been awarding a "research prize to support work on methods aimed at restricting and replacing animal experiments"; the prize carries an award of $€ 15000$. In 2006 the 25 th animal protection research prize will be awarded.

Based at the Federal Institute for Risk Assessment, the Central Office for recording and assessing methods to replace animal experiments was established in 1989 as the first institution of its kind in the world. Its task is to promote potentially successful approaches to developing and validating replacement and complementary methods. The Central Office's budget for doing so was almost doubled between 1990 ( $€ 204200$ ) and 2005 ( $€ 375000$ ). High priority is accorded to replacing animal experiments in official registration and authorisation procedures in which animal experiments are stipulated. The scientists at the Federal Institute for Risk Assessment also undertake successful research work themselves. For example, the Central Office is heavily involved in EU research projects, undertakes research projects as part of major joint projects and takes part in validation studies and collaborative tests within the EU. Furthermore, for many years a database on methods to replace animal experiments has been maintained at the Federal Institute for Risk Assessment; the database is available free of charge to scientists from the research world and industry at http://www.dimdi.de/static/en/db/dbinfo/dbkurz/zt00.htm.

In 2005 in Germany 1822424 animals were used for experiments and other scientific purposes. That represents an increase of 20971 animals or $1.2 \%$ compared with the previous year.

As in previous years, rodents are the largest group at 1573074 animals or $86 \%$. It is striking that up to 2005 their share continually increased from $75 \%$ in 2001 . The number of dogs and cats has increased by 581 and 395 respectively compared with the
previous year. The number of farm animals used has remained constant at around 20000 a year.

Apes have not been used. In the case of old-world monkeys, new-world monkeys and prosimians, there has been an increase of 338 animals compared with the previous year. That is the second highest figure since 2000 . Apes were last reported in Germany in 1991.

The decline by 92270 or $59 \%$ in the number of fish used is encouraging. In particular, there has been a reduction by 64083 fish within basic research and by 15463 fish in toxicological tests to identify environmental risks.

Within biological basic research there has been a reduction by 42014 animals (5.5\%) and within toxicological investigations and tests by 1562 (1.0\%).

No uniform trend is discernible in the case of animals used in the diagnosis of diseases; while their number rose by $158 \%$ to 39013 in 2004 compared with the previous year, it fell again to 13661 in 2005 and was therefore lower than in 2004.

With regard to products or equipment for medicine, dentistry or veterinary medicine, their research and development saw a marked increase by 13869 animals and their manufacture or quality control by 101535 animals.

Of those animals, $58 \%$ were used to research diseases in humans or animals.
For legally stipulated experiments for the manufacture or quality control of products for medicine, dentistry or veterinary medicine, or for toxicological safety tests, $24.9 \%$ of the animals were used.

On behalf of the ministry,
Dr Polten

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 <br> Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6 Animals coming from other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 1084358 | 921971 | 141721 | 18197 | 2469 |  |
|  | Rats (Rattus norvegicus) | 435417 | 339626 | 90339 | 3516 | 1936 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 37761 | 37372 | 389 | 0 | 0 |  |
| 1.d. | Hamsters (Mesocricetus ) | 7916 | 6965 | 861 | 13 | 77 |  |
| 1.e. | Other Rodents (other Rodentia) | 7622 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 103329 | 101939 | 1354 | 4 | 32 | 6532 |
| 1.g. | Cats (Felis catus) | 1023 | 569 | 316 | 0 | 138 | 262 |
| 1.h. | Dogs (Canis familiaris) | 4868 | 2923 | 671 | 0 | 1274 | 1056 |
| 1.i. | Ferrets (Mustela putorius furo) | 560 | 131 | 4 | 0 | 425 | 4 |
| 1.j. | Other Carnivores (other Carnivora) | 235 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 755 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 13166 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 275 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 3517 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 2909 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 99 | 0 | 99 | 0 | 0 | 81 |
| 1.q. | New World Monkeys (Ceboidea) | 408 | 347 | 61 | 0 | 0 | 67 |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 1579 | 120 | 247 | 0 | 1212 | 327 |
| 1.s. | Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. | Other Mammals (other Mammalia) | 115 |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 2457 | 2457 | 0 | 0 | 0 |  |
| 1.v. | Other birds (other Aves) | 39150 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 136 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 10432 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 64337 |  |  |  |  |  |
| 1.z. | TOTAL | 1822424 |  |  |  |  |  |

 updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES
Purpose versus species

|  | $\begin{gathered} \hline 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 <br> Production and quality control of products and devices for human medicine and dentistry | 2.5 <br> Production and quality control of products and devices for veterinary medicine | 2.6 <br> Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8 <br> Education and training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 548649 | 277287 | 106512 | 42650 | 50280 | 4411 | 16146 | 38423 | 1084358 |
| 2.b. | Rats | 101199 | 195642 | 47486 | 11683 | 62982 | 885 | 13472 | 2068 | 435417 |
| 2.c. | Guinea-Pigs | 1907 | 4999 | 14251 | 5921 | 9755 | 11 | 402 | 515 | 37761 |
| 2.d. | Hamsters | 3583 | 2227 | 3 | 1195 | 56 | 6 | 307 | 539 | 7916 |
| 2.e. | Other Rodents | 3161 | 3901 | 0 | 0 | 0 | 6 | 186 | 368 | 7622 |
| 2.f. | Rabbits | 2600 | 7083 | 81097 | 5204 | 4568 | 1188 | 194 | 1395 | 103329 |
| 2.g. | Cats | 293 | 490 | 35 | 38 | 128 | 3 | 13 | 23 | 1023 |
| 2.h. | Dogs | 410 | 1568 | 34 | 245 | 2422 | 63 | 89 | 37 | 4868 |
| 2.i. | Ferrets | 4 | 542 | 0 | 0 | 0 | 0 | 0 | 14 | 560 |
| 2.j. | Other Carnivores | 27 | 0 | 0 | 202 | 0 | 0 | 0 | 6 | 235 |
| 2.k. | Horses, donkeys and cross breds | 385 | 202 | 0 | 2 | 10 | 54 | 102 | 0 | 755 |
| 2.1. | Pigs | 3140 | 4845 | 32 | 985 | 327 | 925 | 1978 | 934 | 13166 |
| 2.m. | Goats | 151 | 43 | 7 | 1 | 2 | 3 | 55 | 13 | 275 |
| 2.n. | Sheep | 882 | 583 | 54 | 101 | 2 | 359 | 104 | 1432 | 3517 |
| 2.0. | Cattle | 435 | 1159 | 0 | 147 | 91 | 734 | 161 | 182 | 2909 |
| 2.p. | Prosimians | 2 | 0 | 0 | 0 | 97 | 0 | 0 | 0 | 99 |
| 2.q. | New World Monkeys | 196 | 89 | 0 | 0 | 122 | 0 | 0 | 1 | 408 |
| 2.r. | Old World Monkeys | 51 | 158 | 0 | 0 | 1299 | 0 | 8 | 63 | 1579 |
| 2.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.t. | Other Mammals | 107 | 7 | 0 | 0 | 0 | 0 | 1 | 0 | 115 |
| 2.u. | Quail | 0 | 0 | 0 | 0 | 2447 | 0 | 0 | 10 | 2457 |
| 2.v. | Other birds | 9089 | 10329 | 690 | 13117 | 1644 | 857 | 1271 | 2153 | 39150 |
| 2.w. | Reptiles | 114 | 13 | 0 | 0 | 0 | 0 | 9 | 0 | 136 |
| 2.x. | Amphibians | 8836 | 0 | 0 | 0 | 0 | 0 | 1596 | 0 | 10432 |
| 2.y. | Fish | 30135 | 0 | 0 | 825 | 23180 | 4156 | 2177 | 3864 | 64337 |
| 2.z. | TOTAL | 715356 | 511167 | 250201 | 82316 | 159412 | 13661 | 38271 | 52040 | 1822424 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Products versus species

|  |  | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminents in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 32474 | 6930 | 10388 | 0 | 0 | 0 | 0 | 10 | 478 | 50280 |
| 3.b. | Rats | 36143 | 10131 | 15018 | 113 | 0 | 0 | 0 | 451 | 1126 | 62982 |
| 3.c. | Guinea-Pigs | 5364 | 2290 | 2061 | 0 | 0 | 0 | 0 | 0 | 40 | 9755 |
| 3.d. | Hamsters | 36 | 20 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 56 |
| 3.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.f. | Rabbits | 3182 | 851 | 501 | 4 | 0 | 0 | 0 | 0 | 30 | 4568 |
| 3.g. | Cats | 128 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 128 |
| 3.h. | Dogs | 2135 | 184 | 103 | 0 | 0 | 0 | 0 | 0 | 0 | 2422 |
| 3.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.k. | Horses, donkeys and cross breds | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 10 |
| 3.1. | Pigs | 303 | 0 | 8 | 0 | 0 | 0 | 0 | 0 | 16 | 327 |
| 3.m. | Goats | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| 3.n. | Sheep | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| 3.0. | Cattle | 91 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 91 |
| 3.p. | Prosimians | 97 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 97 |
| 3.q. | New World Monkeys | 122 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 122 |
| 3.r. | Old World Monkeys | 1299 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1299 |
| 3.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.u. | Quail | 0 | 2447 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2447 |
| 3.v. | Other birds | 60 | 1084 | 0 | 0 | 0 | 0 | 480 | 20 | 0 | 1644 |
| 3.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.y. | Fish | 313 | 8521 | 2664 | 0 | 0 | 0 | 0 | 9744 | 1938 | 23180 |
| 3.z. | TOTAL | 81759 | 32460 | 30743 | 117 | 0 | 0 | 480 | 10225 | 3628 | 159412 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 Studies specific to animal diseases | $\begin{gathered} \hline 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 53032 | 131336 | 161390 | 361742 | 3918 | 711418 |
| 4.b. | Rats | 45836 | 110443 | 9632 | 110670 | 289 | 276870 |
| 4.c. | Guinea-Pigs | 614 | 289 | 37 | 4777 | 144 | 5861 |
| 4.d. | Hamsters | 661 | 1783 | 182 | 2426 | 0 | 5052 |
| 4.e. | Other Rodents | 10 | 1006 | 362 | 3615 | 634 | 5627 |
| 4.f. | Rabbits | 4559 | 221 | 124 | 2725 | 480 | 8109 |
| 4.g. | Cats | 0 | 60 | 0 | 28 | 360 | 448 |
| 4.h. | Dogs | 543 | 3 | 28 | 195 | 955 | 1724 |
| 4.i. | Ferrets | 0 | 0 | 0 | 533 | 0 | 533 |
| 4.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.k. | Horses, donkeys and cross breds | 0 | 0 | 8 | 16 | 451 | 475 |
| 4.1. | Pigs | 2156 | 172 | 118 | 1677 | 2368 | 6491 |
| 4.m. | Goats | 15 | 1 | 3 | 6 | 12 | 37 |
| 4.n. | Sheep | 375 | 9 | 0 | 253 | 933 | 1570 |
| 4.0. | Cattle | 0 | 43 | 0 | 142 | 1884 | 2069 |
| 4.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.q. | New World Monkeys | 16 | 105 | 2 | 129 | 0 | 252 |
| 4.r. | Old World Monkeys | 3 | 18 | 2 | 96 | 0 | 119 |
| 4.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.t. | Other Mammals | 0 | 7 | 0 | 42 | 0 | 49 |
| 4.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.v. | Other birds | 0 | 8 | 0 | 915 | 10965 | 11888 |
| 4.w. | Reptiles | 13 | 0 | 0 | 12 | 78 | 103 |
| 4.x. | Amphibians | 561 | 131 | 16 | 239 | 0 | 947 |
| 4.y. | Fish | 300 | 593 | 0 | 2000 | 6756 | 9649 |
| 4.z. | TOTAL | 108694 | 246228 | 171904 | 492238 | 30227 | 1049291 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

 2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 <br> National legislation <br> specific to a single EC <br> Member State <br> 1) | 6.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 6.4 <br> Member Country of Council of Europe (but not EC) legislation <br> 2) | 6.5 Other legislation | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | 6.7 No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice | 0 | 33677 | 0 | 4357 | 10625 | 1621 | 50280 |
| 6.b. | Rats | 374 | 35528 | 0 | 584 | 24122 | 2374 | 62982 |
| 6.c. | Guinea-Pigs | 0 | 7055 | 0 | 20 | 2487 | 193 | 9755 |
| 6.d. | Hamsters | 0 | 56 | 0 | 0 | 0 | 0 | 56 |
| 6.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.f. | Rabbits | 0 | 3484 | 0 | 0 | 1034 | 50 | 4568 |
| 6.g. | Cats | 102 | 22 | 0 | 0 | 4 | 0 | 128 |
| 6.h. | Dogs | 64 | 999 | 0 | 0 | 1347 | 12 | 2422 |
| 6.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 10 | 10 |
| 6.1. | Pigs | 0 | 139 | 0 | 0 | 172 | 16 | 327 |
| 6.m. | Goats | 0 | 2 | 0 | 0 | 0 | 0 | 2 |
| 6.n. | Sheep | 0 | 2 | 0 | 0 | 0 | 0 | 2 |
| 6.0. | Cattle | 0 | 91 | 0 | 0 | 0 | 0 | 91 |
| 6.p. | Prosimians | 0 | 97 | 0 | 0 | 0 | 0 | 97 |
| 6.q. | New World Monkeys | 0 | 0 | 0 | 0 | 122 | 0 | 122 |
| 6.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 1299 | 0 | 1299 |
| 6.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.u. | Quail | 0 | 1562 | 0 | 0 | 885 | 0 | 2447 |
| 6.v. | Other birds | 0 | 1213 | 0 | 0 | 351 | 80 | 1644 |
| 6.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.y. | Fish | 4770 | 5653 | 0 | 0 | 9865 | 2892 | 23180 |
| 6.z. | TOTAL | 5310 | 89580 | 0 | 4961 | 52313 | 7248 | 159412 |

Examples:
6.2 - France is testing due to a UK (or FR) specific requirement 6.3- UK is testing according to EC legislation 6.4 - Spain is testing due to a Hungarian requirement 6.5 - Sweden is testing due to a US specific requirement 6.6 - Germany is testing due to a Czech requirement (also an EC
columns 6.2-6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.


1) EC Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom
2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| 7.1 Species |  | 7.2 <br> Acute and sub-acute toxicity testing methods (including limit test) |  |  | $\begin{gathered} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 7.4 Skin sensitisatio n | 7.5 Eye irritation | 7.6 Subchronic and chronic toxicity | 7.7 <br> Carcinogenicity | 7.8 <br> Develop- <br> mental toxicity | $\begin{gathered} 7.9 \\ \text { Muta- } \\ \text { genicit } \\ \text { y } \end{gathered}$ | 7.10 Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 7.12 \\ & \text { Other } \end{aligned}$ | $\begin{aligned} & \hline 7.13 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 0 | 33677 | 0 | 4357 | 10625 | 1621 | 50280 | 0 | 33677 | 0 | 4357 | 10625 | 1621 | 50280 |
| 7.b. | Rats | 374 | 35528 | 0 | 584 | 24122 | 2374 | 62982 | 374 | 35528 | 0 | 584 | 24122 | 2374 | 62982 |
| 7.c. | Guinea-Pigs | 0 | 7055 | 0 | 20 | 2487 | 193 | 9755 | 0 | 7055 | 0 | 20 | 2487 | 193 | 9755 |
| 7.d. | Hamsters | 0 | 56 | 0 | 0 | 0 | 0 | 56 | 0 | 56 | 0 | 0 | 0 | 0 | 56 |
| 7.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.f. | Rabbits | 0 | 3484 | 0 | 0 | 1034 | 50 | 4568 | 0 | 3484 | 0 | 0 | 1034 | 50 | 4568 |
| 7.g. | Cats | 102 | 22 | 0 | 0 | 4 | 0 | 128 | 102 | 22 | 0 | 0 | 4 | 0 | 128 |
| 7.h. | Dogs | 64 | 999 | 0 | 0 | 1347 | 12 | 2422 | 64 | 999 | 0 | 0 | 1347 | 12 | 2422 |
| 7.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 10 | 10 | 0 | 0 | 0 | 0 | 0 | 10 | 10 |
| 7.1. | Pigs | 0 | 139 | 0 | 0 | 172 | 16 | 327 | 0 | 139 | 0 | 0 | 172 | 16 | 327 |
| 7.m. | Goats | 0 | 2 | 0 | 0 | 0 | 0 | 2 | 0 | 2 | 0 | 0 | 0 | 0 | 2 |
| 7.n. | Sheep | 0 | 2 | 0 | 0 | 0 | 0 | 2 | 0 | 2 | 0 | 0 | 0 | 0 | 2 |
| 7.0. | Cattle | 0 | 91 | 0 | 0 | 0 | 0 | 91 | 0 | 91 | 0 | 0 | 0 | 0 | 91 |
| 7.p. | Prosimians | 0 | 97 | 0 | 0 | 0 | 0 | 97 | 0 | 97 | 0 | 0 | 0 | 0 | 97 |
| 7.q. | New World Monkeys | 0 | 0 | 0 | 0 | 122 | 0 | 122 | 0 | 0 | 0 | 0 | 122 | 0 | 122 |
| 7.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 1299 | 0 | 1299 | 0 | 0 | 0 | 0 | 1299 | 0 | 1299 |
| 7.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.u. | Quail | 0 | 1562 | 0 | 0 | 885 | 0 | 2447 | 0 | 1562 | 0 | 0 | 885 | 0 | 2447 |
| 7.v. | Other birds | 0 | 1213 | 0 | 0 | 351 | 80 | 1644 | 0 | 1213 | 0 | 0 | 351 | 80 | 1644 |
| 7.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.y. | Fish | 4770 | 5653 | 0 | 0 | 9865 | 2892 | 23180 | 4770 | 5653 | 0 | 0 | 9865 | 2892 | 23180 |
| 7.z. | TOTAL | 5310 | 89580 | 0 | 4961 | 52313 | 7248 | 159412 | 5310 | 89580 | 0 | 4961 | 52313 | 7248 | 159412 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products


## ESTONIA

## Statistical data submitted

The statistical data have been submitted by anneli.harmson@agri.ee
Remark: data were reported in table 1, 2 and 4 only.

## Comments of Estonian authorities

None

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} \hline 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 <br> Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 4350 | 510 | 3460 | 0 | 380 |  |
| 1.b. | Rats (Rattus norvegicus) | 484 | 0 | 484 | 0 | 0 |  |
|  | Guinea-Pigs (Cavia porcellus) | 0 |  |  |  |  |  |
| 1.d. | Hamsters (Mesocricetus ) | 0 |  |  |  |  |  |
| 1.e. | Other Rodents (other Rodentia) | 0 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 66 | 0 | 66 | 0 | 0 | 0 |
| 1.g. | Cats (Felis catus) | 0 |  |  |  |  |  |
| 1.h. | Dogs (Canis familiaris) | 0 |  |  |  |  |  |
| 1.i. | Ferrets (Mustela putorius furo) | 0 |  |  |  |  |  |
| 1.j. | Other Carnivores (other Carnivora) | 0 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 0 |  |  |  |  |  |
| 1.1. | Pigs (Sus) |  |  |  |  |  |  |
| 1.m. | Goats (Capra) | 0 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) |  |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 0 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 |  |  |  |  |  |
| 1.q. | New World Monkeys (Ceboidea) | 0 |  |  |  |  |  |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 0 |  |  |  |  |  |
| 1.s. | Apes (Hominoidea) | 0 |  |  |  |  |  |
| 1.t. | Other Mammals (other Mammalia) |  |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 0 |  |  |  |  |  |
| 1.v. | Other birds (other Aves) |  |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) |  |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) |  |  |  |  |  |  |
| 1.y. | Fish (Pisces) |  |  |  |  |  |  |
| 1.z. | TOTAL | 4900 |  |  |  |  |  |

 updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 Biological studies of a fundamenta 1 nature | 2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6 ) | 2.4 Production and quality control of products and devices for human medicine and dentistry |  | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7Diagnosis of <br> disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 200 | 4150 |  |  |  |  |  |  | 4350 |
| 2.b. | Rats |  | 484 |  |  |  |  |  |  | 484 |
| 2.c. | Guinea-Pigs |  |  |  |  |  |  |  |  | 0 |
| 2.d. | Hamsters |  |  |  |  |  |  |  |  | 0 |
| 2.e. | Other Rodents |  |  |  |  |  |  |  |  | 0 |
| 2.f. | Rabbits |  | 66 |  |  |  |  |  |  | 66 |
| 2.g. | Cats |  |  |  |  |  |  |  |  | 0 |
| 2.h. | Dogs |  |  |  |  |  |  |  |  | 0 |
| 2.i. | Ferrets |  |  |  |  |  |  |  |  | 0 |
| 2.j. | Other Carnivores |  |  |  |  |  |  |  |  | 0 |
| 2.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  | 0 |
| 2.1. | Pigs |  |  |  |  |  |  |  |  | 0 |
| 2.m. | Goats |  |  |  |  |  |  |  |  | 0 |
| 2.n. | Sheep |  |  |  |  |  |  |  |  | 0 |
| 2.o. | Cattle |  |  |  |  |  |  |  |  | 0 |
| 2.p. | Prosimians |  |  |  |  |  |  |  |  | 0 |
| 2.q. | New World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.r. | Old World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.s. | Apes |  |  |  |  |  |  |  |  | 0 |
| 2.t. | Other Mammals |  |  |  |  |  |  |  |  | 0 |
| 2.u. | Quail |  |  |  |  |  |  |  |  | 0 |
| 2.v. | Other birds |  |  |  |  |  |  |  |  | 0 |
| 2.w. | Reptiles |  |  |  |  |  |  |  |  | 0 |
| 2.x. | Amphibians |  |  |  |  |  |  |  |  | 0 |
| 2.y. | Fish |  |  |  |  |  |  |  |  | 0 |
| 2.z. | TOTAL | 200 | 4700 | 0 | 0 | 0 | 0 | 0 | 0 | 4900 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES


## GREECE

## Statistical data submitted

The statistical data have been submitted by the "ҮПОҮРГЕІО ГЕЛРГIА $\Sigma$ ГЕNIKH $\Delta / \mathrm{N} \Sigma \mathrm{H}$ KTHNIATPIKHE" (Ministry of Rural Development and Food, Directorate for Veterinary Care, Drugs \& Practice).

## Comments of Greek authorities

The legal basis for the collection of statistics on the number and use of vertebrate animals for experimental and other scientific purposes in Greece is provided by:

- Presidential Decree No 160/91 (Government Gazette I 64) on the protection of animals used for experimental and other scientific purposes, in accordance with Council Directive 86/609/EEC, and
- Law No 2015/92 (Government Gazette I 30) approving the European Convention on the protection of animals used for experimental and other scientific purposes.

For the collection of statistics relating to the year 2005, the tables, data and glossary of terms set out in European Commission document EL/11/97/04100000 W00 of 24.6.1997 were used. The Ministry of Rural Development and Food, Directorate-General for Veterinary Affairs, Directorate for Veterinary Care, Drugs \& Practice sent them directly to the educational establishments (universities and technological colleges), research centres, healthcare institutions and businesses and pharmaceutical companies which use vertebrate animals for experimental and other scientific purposes. These documents were not sent to cosmetics manufacturers for the year in question, as our department was informed that no cosmetics company uses animals for experimental purposes in Greece.

The total number of animals used in experiments in Greece in 2005 was 926094.
Of these, $97.32 \%$ ( $901^{\circ} 300$ animals) were fish, of which $0.14 \%$ were used to study fundamental biological characteristics and $99.86 \%$ for research and development of medical, dental and veterinary products and appliances (not including toxicological studies).

A further $2.374 \%$ (21 978 animals) were rodents (15 340 mice - accounting for $69.79 \%$, 6024 rats - accounting for $27.4 \%, 574$ guinea pigs - accounting for $2.61 \%$ and 40 other rodents - accounting for $0.18 \%$ ), $36.95 \%$ of which were used to study fundamental biological characteristics, $18.48 \%$ for research and development of medical, dental and veterinary products and appliances, $0.59 \%$ to control the production and quality of medical and dental products and appliances, $25.2 \%$ for toxicological and other safety studies (exclusively rats in this case), $14.84 \%$ for diagnosing illnesses, $0.01 \%$ for education and training purposes and, finally, $0.019 \%$ for other purposes.

Rabbits accounted for $0.13 \%$ of the animals used: (1 255 animals, of which 10 had already been used to take blood samples for the purpose of isolating platelets for further laboratory trials) $48.44 \%$ were used to study fundamental biological characteristics, $2.78 \%$ for research and development of medical, dental and veterinary products and appliances, $1.59 \%$ to control the production and quality of medical and dental products and appliances, $9.32 \%$ to control
the production and quality of veterinary products and appliances, $0.95 \%$ for toxicological and other safety studies, $2.23 \%$ for the diagnosis of illnesses, $16.09 \%$ for education and training purposes and, finally, $18.56 \%$ for other purposes.

Dogs accounted for $0.0015 \%$ ( 14 animals), of which $71.42 \%$ were used for research and development of medical, dental and veterinary products and appliances and $28.58 \%$ for education and training purposes.

Pigs accounted for $0.048 \%$ of the animals used (448 animals), of which $25.67 \%$ were used to study fundamental biological characteristics, $11.16 \%$ for research and development of medical, dental and veterinary products and appliances, $59.37 \%$ for education and training purposes and, finally, $3.79 \%$ for other purposes.

Sheep accounted for $0.001 \%$ of the animals used ( 99 animals), of which $20.2 \%$ were used to study fundamental biological characteristics, $54.54 \%$ for the diagnosis of illnesses, $24.24 \%$ for education and training purposes and $1.01 \%$ for other purposes.

Three Old World Apes were used to study fundamental biological characteristics, of which two can be reused according to the research institution's statement.

Hens accounted for $0.002 \%$ (21 animals), of which $71.42 \%$ were used for the diagnosis of diseases and $28.58 \%$ for education and training purposes.

Amphibians accounted for $0.105 \%$ ( 975 animals), of which $100 \%$ were used for education and training purposes.

Finally, only one (1) equid was used for education and training purposes.
It is apparent from the above data that the two main categories of experiments conducted in Greece are on the one hand, research and development of medical, dental and veterinary products and appliances and on the other, the study of fundamental biological characteristics.

More specifically, vertebrate animals are principally used:

- for research programmes in Greece's Higher Education Institutions and research centres. In particular, a high percentage of fish endemic to the waters of the Mediterranean Sea are used (the main source of the large number of fish referred to above).
- to study each species' fundamental biological characteristics, for which mainly rodents (mice and rats) and rabbits are used.

HEAD OF THE DIRECTORATE FOR VETERINARY CARE, DRUGS \& PRACTICE

## I. PAPADOPOULOS

## TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

## Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4Animals coming from <br> elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | $\begin{gathered} \hline 1.7 \\ \text { Re-used animals } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 15340 | 14050 | 80 |  | 1210 |  |
| 1.b. | Rats (Rattus norvegicus) | 6024 | 5892 |  |  | 132 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 574 | 324 |  |  | 250 |  |
| 1.d. | Hamsters (Mesocricetus ) | 0 |  |  |  |  |  |
| 1.e. | Other Rodents (other Rodentia) | 40 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 1255 | 1255 |  |  |  | 10 |
| 1.g. | Cats (Felis catus) | 0 |  |  |  |  |  |
| 1.h. | Dogs (Canis familiaris) | 14 | 6 | 8 |  |  |  |
| 1.i. | Ferrets (Mustela putorius furo) | 0 |  |  |  |  |  |
| 1.j. | Other Carnivores (other Carnivora) |  |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 1 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 448 |  |  |  |  |  |
| 1.m. | Goats (Capra) |  |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 99 |  |  |  |  |  |
| 1.0. | Cattle (Bos) |  |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 |  |  |  |  |  |
| 1.q. | New World Monkeys (Ceboidea) | 0 |  |  |  |  |  |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 1 |  | 1 |  |  | 2 |
| 1.s. | Apes (Hominoidea) | 0 |  |  |  |  |  |
| 1.t. | Other Mammals (other Mammalia) |  |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 0 |  |  |  |  |  |
| 1.v. | Other birds (other Aves) | 21 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) |  |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 975 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 901300 |  |  |  |  |  |
| 1.z. | TOTAL | 926092 |  |  |  |  |  |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

## Purpose versus species

|  | $\begin{gathered} \hline 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta I nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7Diagnosis of <br> disease | 2.8Education and <br> training | $\begin{gathered} 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 3279 | 3382 | 50 |  | 5324 | 2956 | 138 | 211 | 15340 |
| 2.b. | Rats | 4629 | 641 | 80 |  | 144 | 37 | 280 | 213 | 6024 |
| 2.c. | Guinea-Pigs | 215 |  |  |  | 85 | 270 | 4 |  | 574 |
| 2.d. | Hamsters |  |  |  |  |  |  |  |  | 0 |
| 2.e. | Other Rodents |  | 40 |  |  |  |  |  |  | 40 |
| 2.f. | Rabbits | 608 | 35 | 20 | 117 | 12 | 28 | 202 | 233 | 1255 |
| 2.g. | Cats |  |  |  |  |  |  |  |  | 0 |
| 2.h. | Dogs |  | 10 |  |  |  |  | 4 |  | 14 |
| 2.i. | Ferrets |  |  |  |  |  |  |  |  | 0 |
| 2.j. | Other Carnivores |  |  |  |  |  |  |  |  | 0 |
| 2.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 1 |  | 1 |
| 2.1. | Pigs | 115 | 50 |  |  |  |  | 266 | 17 | 448 |
| 2.m. | Goats |  |  |  |  |  |  |  |  | 0 |
| 2.n. | Sheep | 20 |  |  |  |  | 54 | 24 | 1 | 99 |
| 2.0. | Cattle |  |  |  |  |  |  |  |  | 0 |
| 2.p. | Prosimians |  |  |  |  |  |  |  |  | 0 |
| 2.q. | New World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.r. | Old World Monkeys | 1 |  |  |  |  |  |  |  | 1 |
| 2.s. | Apes |  |  |  |  |  |  |  |  | 0 |
| 2.t. | Other Mammals |  |  |  |  |  |  |  |  | 0 |
| 2.u. | Quail |  |  |  |  |  |  |  |  | 0 |
| 2.v. | Other birds |  |  |  |  |  | 15 | 6 |  | 21 |
| 2.w. | Reptiles |  |  |  |  |  |  |  |  | 0 |
| 2.x. | Amphibians |  |  |  |  |  |  | 975 |  | 975 |
| 2.y. | Fish | 1300 | 900000 |  |  |  |  |  |  | 901300 |
| 2.z. | TOTAL | 10167 | 904158 | 150 | 117 | 5565 | 3360 | 1900 | 675 | 926092 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Products versus species

|  | $\begin{gathered} \hline 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ <br> substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminents in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 105 |  |  |  |  |  |  |  | 5219 | 5324 |
| 3.b. | Rats |  | 84 | 60 |  |  |  |  |  |  | 144 |
| 3.c. | Guinea-Pigs | 85 |  |  |  |  |  |  |  |  | 85 |
| 3.d. | Hamsters |  |  |  |  |  |  |  |  |  | 0 |
| 3.e. | Other Rodents |  |  |  |  |  |  |  |  |  | 0 |
| 3.f. | Rabbits |  |  |  |  |  |  |  |  | 12 | 12 |
| 3.g. | Cats |  |  |  |  |  |  |  |  |  | 0 |
| 3.h. | Dogs |  |  |  |  |  |  |  |  |  | 0 |
| 3.i. | Ferrets |  |  |  |  |  |  |  |  |  | 0 |
| 3.j. | Other Carnivores |  |  |  |  |  |  |  |  |  | 0 |
| 3.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  | 0 |
| 3.1. | Pigs |  |  |  |  |  |  |  |  |  | 0 |
| 3.m. | Goats |  |  |  |  |  |  |  |  |  | 0 |
| 3.n. | Sheep |  |  |  |  |  |  |  |  |  | 0 |
| 3.0. | Cattle |  |  |  |  |  |  |  |  |  | 0 |
| 3.p. | Prosimians |  |  |  |  |  |  |  |  |  | 0 |
| 3.q. | New World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.s. | Apes |  |  |  |  |  |  |  |  |  | 0 |
| 3.t. | Other Mammals |  |  |  |  |  |  |  |  |  | 0 |
| 3.u. | Quail |  |  |  |  |  |  |  |  |  | 0 |
| 3.v. | Other birds |  |  |  |  |  |  |  |  |  | 0 |
| 3.w. | Reptiles |  |  |  |  |  |  |  |  |  | 0 |
| 3.x. | Amphibians |  |  |  |  |  |  |  |  |  | 0 |
| 3.y. | Fish |  |  |  |  |  |  |  |  |  | 0 |
| 3.z. | TOTAL | 190 | 84 | 60 | 0 | 0 | 0 | 0 | 0 | 5231 | 5565 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3 Human nervous and mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | $\stackrel{4.5}{\text { Other human diseases }}$ | 4.6 <br> Studies specific to animal diseases | $4.7$ <br> Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 95 | 1458 | 410 | 2950 | 300 | 5213 |
| 4.b. | Rats | 65 | 102 |  | 814 |  | 981 |
| 4.c. | Guinea-Pigs |  |  |  |  | 270 | 270 |
| 4.d. | Hamsters |  |  |  |  |  | 0 |
| 4.e. | Other Rodents |  |  | 40 |  |  | 40 |
| 4.f. | Rabbits | 162 |  |  | 321 | 28 | 511 |
| 4.g. | Cats |  |  |  |  |  | 0 |
| 4.h. | Dogs |  |  |  |  |  | 0 |
| 4.i. | Ferrets |  |  |  |  |  | 0 |
| 4.j. | Other Carnivores |  |  |  |  |  | 0 |
| 4.k. | Horses, donkeys and cross breds |  |  |  |  |  | 0 |
| 4.1. | Pigs | 36 |  |  | 79 |  | 115 |
| 4.m. | Goats |  |  |  |  |  | 0 |
| 4.n. | Sheep |  |  |  |  | 54 | 54 |
| 4.0. | Cattle |  |  |  |  |  | 0 |
| 4.p. | Prosimians |  |  |  |  |  | 0 |
| 4.q. | New World Monkeys |  |  |  |  |  | 0 |
| 4.r. | Old World Monkeys |  |  |  |  |  | 0 |
| 4.s. | Apes |  |  |  |  |  | 0 |
| 4.t. | Other Mammals |  |  |  |  |  | 0 |
| 4.u. | Quail |  |  |  |  |  | 0 |
| 4.v. | Other birds |  |  |  |  | 15 | 15 |
| 4.w. | Reptiles |  |  |  |  |  | 0 |
| 4.x. | Amphibians |  |  |  |  |  | 0 |
| 4.y. | Fish |  |  |  |  | 900000 | 900000 |
| 4.z. | TOTAL | 358 | 1560 | 450 | 4164 | 900667 | 907199 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | $5.4$ <br> Member Country of Council of Europe (but not EC) legislation <br> 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice |  |  |  |  |  | 50 | 50 |
| 5.b. | Rats | 80 |  |  |  |  |  | 80 |
| 5.c. | Guinea-Pigs |  |  |  |  |  |  | 0 |
| 5.d. | Hamsters |  |  |  |  |  |  | 0 |
| 5.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 5.f. | Rabbits |  | 117 |  |  |  | 20 | 137 |
| 5.g. | Cats |  |  |  |  |  |  | 0 |
| 5.h. | Dogs |  |  |  |  |  |  | 0 |
| 5.i. | Ferrets |  |  |  |  |  |  | 0 |
| 5.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 5.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 5.1. | Pigs |  |  |  |  |  |  | 0 |
| 5.m. | Goats |  |  |  |  |  |  | 0 |
| 5.n. | Sheep |  |  |  |  |  |  | 0 |
| 5.0. | Cattle |  |  |  |  |  |  | 0 |
| 5.p. | Prosimians |  |  |  |  |  |  | 0 |
| 5.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 5.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
| 5.s. | Apes |  |  |  |  |  |  | 0 |
| 5.t. | Other Mammals |  |  |  |  |  |  | 0 |
| 5.u. | Quail |  |  |  |  |  |  | 0 |
| 5.v. | Other birds |  |  |  |  |  |  | 0 |
| 5.w. | Reptiles |  |  |  |  |  |  | 0 |
| 5.x. | Amphibians |  |  |  |  |  |  | 0 |
| 5.y. | Fish |  |  |  |  |  |  | 0 |
| 5.z. | TOTAL | 80 | 117 | 0 | 0 | 0 | 70 | 267 |

Examples:
5.2 - France is testing due to a UK (or FR) specific requirement 5.3 - UK is testing according to EC legislation 5.4 - Spain is testing due to a Hungarian requirement 5.5 - Sweden is testing due to a US specific requirement 5.6 - Germany is testing due to a Czech requirement (also an EC

Note: columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

## TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 National legislation specific to a single EC Member State 1) | 6.3 EC legislation including European Pharmacopoeia (requirements) | 6.4 <br> Member Country of Council <br> of Europe (but not EC) <br> legislation <br> 2) | $\stackrel{6.5}{\text { Other legislation }}$ | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | 6.7 No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice |  | 105 |  |  | 5219 |  | 5324 |
|  | Rats | 89 | 55 |  |  |  |  | 144 |
|  | Guinea-Pigs |  | 85 |  |  |  |  | 85 |
| 6.d. | Hamsters |  |  |  |  |  |  | 0 |
| 6.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 6.f. | Rabbits |  |  |  |  |  | 12 | 12 |
| 6.g. | Cats |  |  |  |  |  |  | 0 |
|  | Dogs |  |  |  |  |  |  | 0 |
| 6.i. | Ferrets |  |  |  |  |  |  | 0 |
| 6.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 6.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 6.1. | Pigs |  |  |  |  |  |  | 0 |
| 6.m. | Goats |  |  |  |  |  |  | 0 |
| 6.n. | Sheep |  |  |  |  |  |  | 0 |
|  | Cattle |  |  |  |  |  |  | 0 |
| 6.p. | Prosimians |  |  |  |  |  |  | 0 |
| 6.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 6.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
|  | Apes |  |  |  |  |  |  | 0 |
|  | Other Mammals |  |  |  |  |  |  | 0 |
| 6.u. | Quail |  |  |  |  |  |  | 0 |
| 6.v. | Other birds |  |  |  |  |  |  | 0 |
| 6.w. | Reptiles |  |  |  |  |  |  | 0 |
|  | Amphibians |  |  |  |  |  |  | 0 |
| 6.y. | Fish |  |  |  |  |  |  | 0 |
| 6.z. | TOTAL | 89 | 245 | 0 | 0 | 5219 | 12 | 5565 |
| Examples: 6.2 - France is testing due to a UK (or FR) specific requirement <br> 6.3 - UK is testing according to EC legislation <br> 6.4 - Spain is testing due to a Hungarian requirement <br> 6.5 - Sweden is testing due to a US specific requirement <br> 6.6 - Germany is testing due to a Czech requirement (also an EC requirement) |  |  |  | Note: $\quad$ columns 6.2 - 6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. <br> Example: a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium. |  |  |  |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| 7.1 Species |  | 7.2Acute and sub-acute toxicity testing methods <br> (including limit test) |  |  | $\begin{array}{c\|} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{array}$ | 7.4Skinsensitisation | 7.5Eyeirritation | 7.6Sub-chronic andchronictoxicity | 7.7Carcinogenicity | 7.8 <br> Developmental toxicity | 7.9 <br> Mutagenicit <br> y | 7.10 <br> Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $7.12$ <br> Other | $7.13$ <br> Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  | $\begin{aligned} & \text { 7.2.1. } \\ & \text { LD50, } \\ & \text { LC50 } \end{aligned}$ | 7.2.2 <br> Other lethal <br> methods | 7.2.3 <br> Non lethal clinical signs methods |  |  |  |  |  |  |  |  |  |  |  |
| 7.a. | Mice |  | 5219 |  |  |  |  |  |  |  |  |  |  | 105 | 5324 |
| 7.b. | Rats |  |  | 34 |  |  |  | 60 |  |  | 50 |  |  |  | 144 |
| 7.c. | Guinea-Pigs |  |  |  |  |  |  |  |  |  |  |  |  | 85 | 85 |
| 7.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.e. | Other Rodents |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.f. | Rabbits |  |  |  |  |  |  |  |  |  |  |  |  | 12 | 12 |
| 7.g. | Cats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.h. | Dogs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.1. | Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.m. | Goats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.n. | Sheep |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.0. | Cattle |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.s. | Apes |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.u. | Quail |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.v. | Other birds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.y. | Fish |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.z. | TOTAL | 0 | 5219 | 34 | 0 | 0 | 0 | 60 | 0 | 0 | 50 | 0 | 0 | 202 | 5565 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products

| $\begin{gathered} 8.1 \\ \text { Products } \end{gathered}$ | 8.2Acute and sub-acute toxicity testing <br> methods (including limit test) |  |  | $\begin{gathered} \hline 8.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 8.4 Skin sensitisatio n | 8.5 Eye irritation |  | $8.7$ <br> Carcino genicity | $8.8$ <br> Developmental toxicity | $\begin{gathered} 8.9 \\ \text { Muta- } \\ \text { genicit } \\ y \end{gathered}$ | 8.10 <br> Reproductive toxicity | 8.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{gathered} 8.12 \\ \text { Other } \end{gathered}$ | $\begin{gathered} \hline 8.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine |  |  |  |  |  |  |  |  |  |  |  |  | 202 | 202 |
| 8.b. Products/substances used or intended to be used mainly in agriculture |  |  | 84 |  |  |  |  |  |  |  |  |  |  | 84 |
| 8.c. $\begin{aligned} & \text { Products/substances used or intended to } \\ & \text { be used mainly in industry }\end{aligned}$ |  |  |  |  |  |  | 60 |  |  |  |  |  |  | 60 |
| 8.d. Products/substances used or intended to be used mainly in the household |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.f. Products/substances used or intended to be used mainly as additives in food for human consumption |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.g.Products/substances used or intended to <br> be used mainly as additives in food for <br> animal consumption |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.i. Other toxicological or safety evaluations |  | 5219 |  |  |  |  |  |  |  |  |  |  |  | 5219 |
| 8.j. TOTAL | 0 | 5219 | 84 | 0 | 0 | 0 | 60 | 0 | 0 | 0 | 0 | 0 | 202 | 5565 |

## SPAIN

## Statistical data submitted

The Statistical data have been provided by the: "Ministerio de Agricultura, Pesca y Alimentación, Subdirección General de Ordenacion de explotaciones" (Ministry of Agriculture, Fisheries and Food, Sub-directorate of Management of Developments).

## Comments of Spanish authorities

None

## TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

## Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | $\begin{gathered} 1.7 \\ \text { Re-used animals } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 393217 | 357390 | 31627 | 22 | 4178 |  |
| 1.b. | Rats (Rattus norvegicus) | 125754 | 113623 | 10478 | 0 | 1653 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 16780 | 14321 | 2459 | 0 | 0 |  |
| 1.d. | Hamsters (Mesocricetus ) | 908 | 877 | 31 | 0 | 0 |  |
| 1.e. | Other Rodents (other Rodentia) | 294 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 11878 | 11111 | 767 | 0 | 0 | 0 |
| 1.g. | Cats (Felis catus) | 168 | 84 |  | 0 | 84 | 0 |
| 1.h. | Dogs (Canis familiaris) | 685 | 525 | 151 | 0 | 9 | 0 |
| 1.i. | Ferrets (Mustela putorius furo) | 237 | 155 | 82 | 0 | 0 | 0 |
| 1.j. | Other Carnivores (other Carnivora) | 0 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 42 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 4818 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 119 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 821 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 294 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. | New World Monkeys (Ceboidea) | 1 | 0 | 1 | 0 | 0 | 0 |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 81 | 52 | 29 | 0 | 0 | 0 |
| 1.s. | Apes (Hominoidea) | 2 | 2 | 0 | 0 | 0 | 0 |
| 1.t. | Other Mammals (other Mammalia) | 60 |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 1 | 1 | 0 | 0 | 0 |  |
| 1.v. | Other birds (other Aves) | 8424 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 10 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 419 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 30584 |  |  |  |  |  |
| 1.z. | TOTAL | 595597 | 498141 | 45625 | 22 | 5924 | 0 |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

## Purpose versus species

|  | $\begin{gathered} \hline 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7Diagnosis of <br> disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 130339 | 115641 | 6680 | 17599 | 62528 | 51405 | 8325 | 11300 | 403817 |
| 2.b. | Rats | 51885 | 39077 | 2204 | 810 | 8379 | 5252 | 5085 | 2843 | 115535 |
| 2.c. | Guinea-Pigs | 342 | 8343 | 1142 | 3310 | 3510 | 92 | 28 | 13 | 16780 |
| 2.d. | Hamsters | 493 | 52 | 0 | 264 | 0 | 87 | 12 | 0 | 908 |
| 2.e. | Other Rodents | 100 | 166 | 0 | 0 | 0 | 0 | 28 | 0 | 294 |
| 2.f. | Rabbits | 854 | 2674 | 30 | 2106 | 5026 | 51 | 1008 | 90 | 11839 |
| 2.g. | Cats | 76 | 3 | 13 | 0 | 0 | 0 | 3 | 73 | 168 |
| 2.h. | Dogs | 44 | 81 | 6 | 0 | 272 | 5 | 18 | 0 | 426 |
| 2.i. | Ferrets | 17 | 220 | 0 | 0 | 0 | 0 | 0 | 0 | 237 |
| 2.j. | Other Carnivores | 0 | 0 | 0 |  | 0 | 0 | 0 | 0 | 0 |
| 2.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 42 | 0 | 0 | 0 | 0 | 42 |
| 2.1. | Pigs | 288 | 1531 | 0 | 921 | 368 | 40 | 1200 | 387 | 4735 |
| 2.m. | Goats | 16 | 7 | 0 | 0 | 24 | 0 | 0 | 72 | 119 |
| 2.n. | Sheep | 17 | 94 | 0 | 571 | 62 | 0 | 75 | 2 | 821 |
| 2.0. | Cattle | 0 | 104 | 0 | 190 | 0 | 0 | 0 | 0 | 294 |
| 2.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.q. | New World Monkeys | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| 2.r. | Old World Monkeys | 23 | 21 | 0 | 0 | 37 | 0 | 0 | 0 | 81 |
| 2.s. | Apes | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| 2.t. | Other Mammals | 0 | 0 | 0 | 60 | 0 | 0 | 0 | 0 | 60 |
| 2.u. | Quail | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| 2.v. | Other birds | 94 | 2682 | 0 | 4343 | 40 | 15 | 50 | 1200 | 8424 |
| 2.w. | Reptiles | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 10 |
| 2.x. | Amphibians | 351 | 0 | 0 | 0 | 0 | 0 | 0 | 68 | 419 |
| 2.y. | Fish | 28349 | 700 | 0 | 0 | 1269 | 0 | 266 | 0 | 30584 |
| 2.z. | TOTAL | 213302 | 171396 | 10075 | 30216 | 81515 | 56947 | 16098 | 16048 | 595597 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Products versus species

|  | $\begin{gathered} 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminents in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 21400 | 24 | 0 | 0 | 0 | 0 | 725 | 1285 | 40597 | 64031 |
| 3.b. | Rats | 3870 | 359 | 768 | 0 | 0 | 0 | 0 | 230 | 1375 | 6602 |
| 3.c. | Guinea-Pigs | 3287 | 0 | 63 | 0 | 0 | 0 | 0 | 0 | 160 | 3510 |
| 3.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.f. | Rabbits | 5187 | 0 | 111 | 0 | 75 | 0 | 0 | 0 | 45 | 5418 |
| 3.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.h. | Dogs | 179 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 77 | 256 |
| 3.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.1. | Pigs | 251 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 15 | 266 |
| 3.m. | Goats | 24 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 24 |
| 3.n. | Sheep | 62 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 62 |
| 3.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.r. | Old World Monkeys | 37 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 37 |
| 3.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.v. | Other birds | 40 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 40 |
| 3.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.y. | Fish | 100 | 237 | 0 | 560 | 0 | 0 | 0 | 372 | 0 | 1269 |
| 3.z. | TOTAL | 34437 | 620 | 942 | 560 | 75 | 0 | 725 | 1887 | 42269 | 81515 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 Studies specific to animal diseases | $\begin{gathered} 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 5844 | 13808 | 87612 | 80515 | 3839 | 191618 |
| 4.b. | Rats | 5938 | 15263 | 1538 | 36055 | 579 | 59373 |
| 4.c. | Guinea-Pigs | 44 | 286 | 110 | 637 | 325 | 1402 |
| 4.d. | Hamsters | 0 | 87 | 52 | 46 | 143 | 328 |
| 4.e. | Other Rodents | 0 | 120 | 0 | 74 | 448 | 642 |
| 4.f. | Rabbits | 180 | 3 | 66 | 803 | 474 | 1526 |
| 4.g. | Cats | 0 | 18 | 0 | 3 | 0 | 21 |
| 4.h. | Dogs | 27 | 2 | 3 | 135 | 12 | 179 |
| 4.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.k. | Horses, donkeys and cross breds | 0 | 17 | 0 | 0 | 0 | 17 |
| 4.1. | Pigs | 273 | 0 | 21 | 468 | 420 | 1182 |
| 4.m. | Goats | 40 | 24 | 0 | 7 | 0 | 71 |
| 4.n. | Sheep | 0 | 0 | 0 | 45 | 55 | 100 |
| 4.0. | Cattle | 0 | 0 | 0 | 0 | 14 | 14 |
| 4.p. | Prosimians | 0 | 1 | 0 | 0 | 0 | 1 |
| 4.q. | New World Monkeys | 0 | 3 | 0 | 0 | 0 | 3 |
| 4.r. | Old World Monkeys | 0 | 0 | 0 | 28 | 0 | 28 |
| 4.s. | Apes | 0 | 0 | 0 | 2 | 0 | 2 |
| 4.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.u. | Quail | 0 | 57 | 0 | 0 | 0 | 57 |
| 4.v. | Other birds | 0 | 0 | 0 | 0 | 1300 | 1300 |
| 4.w. | Reptiles | 0 | 45 | 0 | 0 | 0 | 45 |
| 4.x. | Amphibians | 0 | 192 | 50 | 50 | 0 | 292 |
| 4.y. | Fish | 0 |  | 200 | 300 | 3966 | 4466 |
| 4.z. | TOTAL | 12346 | 29926 | 89652 | 119168 | 11575 | 262667 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 EC legislation including European Pharmacopoeia (requirements) | 5.4 Member Country of Council of Europe (but not EC) legislation 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice | 66 | 21771 | 0 | 0 | 5 | 2437 | 24279 |
| 5.b. | Rats | 0 | 1342 | 0 | 1672 | 0 | 0 | 3014 |
| 5.c. | Guinea-Pigs | 0 | 3340 | 0 | 1058 | 0 | 54 | 4452 |
| 5.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 264 | 264 |
| 5.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.f. | Rabbits | 2 | 1563 | 0 | 0 | 0 | 571 | 2136 |
| 5.g. | Cats | 0 | 0 | 0 | 13 | 0 | 0 | 13 |
| 5.h. | Dogs | 0 | 0 | 0 | 0 | 0 | 6 | 6 |
| 5.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.k. | Horses, donkeys and cross breds | 0 | 42 | 0 | 0 | 0 | 0 | 42 |
| 5.1. | Pigs | 22 | 553 | 0 | 0 | 20 | 326 | 921 |
| 5.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.n. | Sheep | 0 | 571 | 0 | 0 | 0 | 0 | 571 |
| 5.0. | Cattle | 0 | 190 | 0 | 0 | 0 | 0 | 190 |
| 5.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.t. | Other Mammals | 0 | 60 | 0 | 0 | 0 | 0 | 60 |
| 5.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.v. | Other birds | 0 | 3349 | 0 | 681 | 0 | 313 | 4343 |
| 5.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.y. | Fish | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.z. | TOTAL | 90 | 32781 | 0 | 3424 | 25 | 3971 | 40291 |

Examples: 5.2 - France is testing due to a UK (or FR) specific requirement 5.3 - UK is testing according to EC legislation 5.4 - Spain is testing due to a Hungarian requirement 5.5 - Sweden is testing due to a US specific requirement 5.6 - Germany is testing due to a Czech requirement (also an EC

Note: columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

## TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 National legislation specific to a single EC Member State 1) | 6.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 6.4 <br> Member Country of Council <br> of Europe (but not EC) <br> legislation <br> 2) | 6.5 Other legislation | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | $\begin{gathered} \hline 6.7 \\ \text { No regulatory } \\ \text { requirements } \end{gathered}$ | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice | 308 | 13299 | 0 | 441 | 46381 | 3602 | 64031 |
| 6.b. | Rats | 96 | 1195 | 0 | 1509 | 2391 | 1411 | 6602 |
| 6.c. | Guinea-Pigs | 41 | 703 | 0 | 287 | 2479 | 0 | 3510 |
| 6.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.f. | Rabbits | 133 | 194 | 0 | 175 | 4760 | 156 | 5418 |
| 6.g. | Cats | 0 | 0 | 0 | 0 | 0 | 23 | 23 |
| 6.h. | Dogs | 0 | 67 | 0 | 10 | 156 | 0 | 233 |
| 6.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.1. | Pigs | 6 | 244 | 0 | 0 | 16 | 0 | 266 |
| 6.m. | Goats | 0 | 24 | 0 | 0 | 0 | 0 | 24 |
| 6.n. | Sheep | 2 | 42 | 0 | 0 | 0 | 18 | 62 |
| 6.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 32 | 5 | 37 |
| 6.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.v. | Other birds | 0 | 0 | 0 | 0 | 0 | 40 | 40 |
| 6.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.y. | Fish | 0 | 0 | 0 | 72 | 1197 | 0 | 1269 |
| 6.z. | TOTAL | 586 | 15768 | 0 | 2494 | 57412 | 5255 | 81515 |

Examples: $\quad 6.2$ - France is testing due to a UK (or FR) specific requirement 6.3-UK is testing according to EC legislation 6.4 - Spain is testing due to a Hungarian requirement 6.5 - Sweden is testing due to a US specific requirement 6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note: columns 6.2-6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2Acute and sub-acute toxicity testing methods(including limit test) |  |  | 7.3 Skin irritation | 7.4 Skin sensitisatio n | $\begin{gathered} \hline 7.5 \\ \text { Eye } \\ \text { irritation } \end{gathered}$ | 7.6 Sub- chronic and chronic toxicity | $7.7$ <br> Carcinogenicity | $7.8$ <br> Developmental toxicity | 7.9 <br> Mutagenicit y | 7.10 Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{gathered} \hline 7.12 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 7.13 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 9430 | 35486 | 1016 | 0 | 40 | 0 | 0 | 674 | 0 | 24 | 0 | 0 | 17361 | 64031 |
| 7.b. | Rats | 831 | 365 | 601 | 135 | 0 | 0 | 1057 | 96 | 0 | 0 | 567 | 0 | 2956 | 6608 |
| 7.c. | Guinea-Pigs | 0 | 399 | 12 | 16 | 463 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2614 | 3504 |
| 7.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.f. | Rabbits | 6 | 16 | 24 | 282 | 0 | 64 | 6 | 0 | 113 | 0 | 0 | 0 | 4907 | 5418 |
| 7.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.h. | Dogs | 0 | 0 | 0 | 0 | 0 | 0 | 156 | 0 | 0 | 0 | 0 | 0 | 100 | 256 |
| 7.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.1. | Pigs | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 266 | 266 |
| 7.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 24 | 24 |
| 7.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 62 | 62 |
| 7.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 37 | 0 | 0 | 0 | 0 | 0 | 0 | 37 |
| 7.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.v. | Other birds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 40 | 40 |
| 7.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.y. | Fish | 287 | 0 | 0 | 0 | 0 | 0 | 860 | 0 | 50 | 0 | 72 | 0 | 0 | 1269 |
| 7.z. | TOTAL | 10554 | 36266 | 1653 | 433 | 503 | 64 | 2116 | 770 | 163 | 24 | 639 | 0 | 28330 | 81515 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products


## FRANCE

## Statistical data submitted

The statistical data have been submitted by the "Ministère de la Recherche et des Nouvelles Technologies" (Ministry for Research and New Technologies).

## Comments of the French authorities

This study was realized by the EFICOM Markétudes Company for the Research and University Education Ministry.

The number of animals used in France since 1999 is steady and about 2.2 billion. It represents a decrease of $40 \%$ in comparison with the figures of the first study in 1990. In 2004, a slight increasing tendency could have been observed which led the figures to their 1999 rounded values. Since 1999, the amount of rodents used is steady ( 2.1 billion); and even if some animal groups are more often used (the amount of fishes and amphibian has doubled), there is a reversal tendency for other species (the amount of horses and oxen decreased by $50 \%$, and cats by $25 \%$ ). In return, the use of primates becomes more and more significant and is certainly not going to weak because of their scientific interests.

Concerning the study results, when significant differences were revealed between the 2001 and the 2004 figures, some verification were done in order to know what was the origin of these sudden evolutions. Each time these differences were explained by either new activity, for example the obtainment of therapeutic antibodies for rabbits increased by $74 \%$, or the closure of laboratories. They could be explained too by mistakes typed in the 2001 study report (concerning reptiles for example). The other variations are not significant and support the figures provided by experimental centres and laboratories.

This study allows estimating that public sector uses a third of the total amount of animals, of which $65 \%$ is for basic research and education. On the other hand, private sector uses the remaining two third, of which $37 \%$ are dedicated to research and development, $46 \%$ to production and control, and $11 \%$ to toxicological evaluations.

This study allows showing too that centres for animal experimentation are about 450 (it can vary depending on juridical conventions that link laboratories to these centres). It represents a third of the figure established in 1990. This decrease of the amount of experimental centres shows that henceforth laboratories are regrouped in order to dispose of centralized installations and competent staff. The «disappearance» of 900 experimental animal houses shows the pressure brought by the associations and the concerned authorities for fifteen years. It was engendered by very significant investments to come up to the current sanitary, ethic and scientific expectances. Of course, this diminution did not obviously drive to a decrease of the amount of animals with the same proportion, but it set practices that assure respect and well-being to animals.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} \hline 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 1510334 | 1409076 | 21809 | 2383 | 77066 |  |
| 1.b. | Rats (Rattus norvegicus) | 424387 | 411068 | 2128 | 25 | 11166 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 79350 | 56862 | 16679 | 0 | 5809 |  |
| 1.d. | Hamsters (Mesocricetus ) | 8691 | 7672 | 75 | 0 | 944 |  |
| 1.e. | Other Rodents (other Rodentia) | 12683 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 93282 | 92897 | 10 | 0 | 375 | 1542 |
| 1.g. | Cats (Felis catus) | 1313 | 622 | 9 | 0 | 682 | 408 |
| 1.h. | Dogs (Canis familiaris) | 5539 | 3662 | 20 | 0 | 1857 | 690 |
| 1.i. | Ferrets (Mustela putorius furo) | 155 | 85 | 0 | 0 | 70 | 0 |
| 1.j. | Other Carnivores (other Carnivora) | 0 |  |  |  |  |  |
|  | Horses, donkeys and cross breds (Equidae) | 223 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 6587 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 442 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 4992 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 1296 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 578 | 578 | 0 | 0 | 0 | 30 |
| 1.q. | New World Monkeys (Ceboidea) | 433 | 340 | 20 | 13 | 60 | 96 |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 2778 | 809 | 38 | 0 | 1931 | 427 |
| 1.s. | Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. | Other Mammals (other Mammalia) | 0 |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 4023 | 3983 | 0 | 0 | 40 | 0 |
| 1.v. | Other birds (other Aves) | 102240 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 0 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 15675 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 50397 |  |  |  |  |  |
| 1.z. | TOTAL | 2325398 |  |  |  |  |  |

 list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

## Purpose versus species

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | $\begin{gathered} 2.7 \\ \begin{array}{c} \text { Diagnosis of } \\ \text { disease } \end{array} \end{gathered}$ | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 351428 | 404603 | 475247 | 59199 | 71036 | 66658 | 41988 | 40175 | 1510334 |
| 2.b. | Rats | 73253 | 205258 | 19913 | 14031 | 69933 | 497 | 15714 | 25788 | 424387 |
| 2.c. | Guinea-Pigs | 1404 | 6127 | 50991 | 6373 | 13122 | 7 | 417 | 909 | 79350 |
| 2.d. | Hamsters | 2043 | 3320 | 151 | 2103 | 144 | 910 | 12 | 8 | 8691 |
| 2.e. | Other Rodents | 745 | 10645 | 0 | 0 | 0 | 27 | 0 | 1266 | 12683 |
| 2.f. | Rabbits | 1246 | 9686 | 61349 | 3334 | 10328 | 1123 | 1689 | 4527 | 93282 |
| 2.g. | Cats | 53 | 396 | 0 | 458 | 24 | 0 | 9 | 373 | 1313 |
| 2.h. | Dogs | 106 | 1062 | 148 | 491 | 3427 | 0 | 32 | 273 | 5539 |
| 2.i. | Ferrets | 30 | 55 | 29 | 0 | 41 | 0 | 0 | 0 | 155 |
| 2.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.k. | Horses, donkeys and cross breds | 0 | 21 | 87 | 8 | 0 | 0 | 91 | 16 | 223 |
| 2.1. | Pigs | 159 | 2421 | 4 | 1407 | 1002 | 1 | 350 | 1243 | 6587 |
| 2.m. | Goats | 26 | 106 | 77 | 0 | 10 | 0 | 23 | 200 | 442 |
| 2.n. | Sheep | 731 | 936 | 3062 | 0 | 10 | 26 | 111 | 116 | 4992 |
| 2.0. | Cattle | 56 | 461 | 1 | 11 | 92 | 20 | 141 | 514 | 1296 |
| 2.p. | Prosimians | 382 | 0 | 0 | 0 | 0 | 0 | 0 | 196 | 578 |
| 2.q. | New World Monkeys | 24 | 121 | 35 | 0 | 168 | 0 | 5 | 80 | 433 |
| 2.r. | Old World Monkeys | 238 | 216 | 326 | 0 | 1874 | 0 | 29 | 95 | 2778 |
| 2.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.u. | Quail | 20 | 0 | 0 | 0 | 0 | 0 | 100 | 3903 | 4023 |
| 2.v. | Other birds | 3768 | 10718 | 10857 | 37069 | 36332 | 435 | 1209 | 1852 | 102240 |
| 2.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.x. | Amphibians | 4760 | 53 | 0 | 0 | 500 | 0 | 9362 | 1000 | 15675 |
| 2.y. | Fish | 41140 | 0 | 0 | 0 | 4948 | 0 | 1439 | 2870 | 50397 |
| 2.z. | TOTAL | 481612 | 656205 | 622277 | 124484 | 212991 | 69704 | 72721 | 85404 | 2325398 |

## TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Products versus species

|  | $\begin{gathered} 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminents in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 39549 | 7321 | 5868 | 0 | 1797 | 516 | 123 | 2438 | 13424 | 71036 |
| 3.b. | Rats | 44318 | 3177 | 5693 | 16 | 2226 | 229 | 0 | 1565 | 12709 | 69933 |
| 3.c. | Guinea-Pigs | 4353 | 445 | 3832 | 177 | 940 | 27 | 0 | 0 | 3348 | 13122 |
| 3.d. | Hamsters | 142 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 144 |
| 3.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.f. | Rabbits | 4796 | 696 | 1319 | 106 | 533 | 0 | 0 | 0 | 2878 | 10328 |
| 3.g. | Cats | 24 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 24 |
| 3.h. | Dogs | 2623 | 134 | 108 | 0 | 0 | 0 | 0 | 0 | 562 | 3427 |
| 3.i. | Ferrets | 41 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 41 |
| 3.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.1. | Pigs | 303 | 0 | 39 | 0 | 0 | 0 | 444 | 83 | 133 | 1002 |
| 3.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 10 |
| 3.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 10 |
| 3.0. | Cattle | 67 | 0 | 0 | 0 | 0 | 0 | 25 | 0 | 0 | 92 |
| 3.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.q. | New World Monkeys | 168 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 168 |
| 3.r. | Old World Monkeys | 970 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 898 | 1874 |
| 3.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.v. | Other birds | 262 | 0 | 98 | 0 | 0 | 0 | 30519 | 366 | 5087 | 36332 |
| 3.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.x. | Amphibians | 0 | 400 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | 500 |
| 3.y. | Fish | 0 | 2848 | 2000 | 0 | 0 | 0 | 0 | 100 | 0 | 4948 |
| 3.z. | TOTAL | 97616 | 15021 | 18965 | 299 | 5496 | 772 | 31221 | 4562 | 39039 | 212991 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

## Main categories versus species

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | $\stackrel{4.5}{\text { Other human diseases }}$ | 4.6 <br> Studies specific to animal diseases | $\begin{gathered} \hline 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 69470 | 226646 | 154806 | 307007 | 64760 | 822689 |
| 4.b. | Rats | 47369 | 112450 | 17732 | 99236 | 2221 | 279008 |
| 4.c. | Guinea-Pigs | 1719 | 924 | 149 | 2980 | 1766 | 7538 |
| 4.d. | Hamsters | 1078 | 1117 | 0 | 2031 | 2047 | 6273 |
| 4.e. | Other Rodents | 0 | 10633 | 0 | 114 | 670 | 11417 |
| 4.f. | Rabbits | 3349 | 0 | 93 | 4504 | 4109 | 12055 |
| 4.g. | Cats | 0 | 14 | 0 | 127 | 308 | 449 |
| 4.h. | Dogs | 130 | 36 | 11 | 654 | 337 | 1168 |
| 4.i. | Ferrets | 0 | 0 | 0 | 85 | 0 | 85 |
| 4.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 21 | 21 |
| 4.1. | Pigs | 830 | 1 | 6 | 245 | 1499 | 2581 |
| 4.m. | Goats | 9 | 0 | 0 | 1 | 122 | 132 |
| 4.n. | Sheep | 152 | 40 | 0 | 116 | 1385 | 1693 |
| 4.0. | Cattle | 1 | 0 | 0 | 0 | 536 | 537 |
| 4.p. | Prosimians | 0 | 382 | 0 | 0 | 0 | 382 |
| 4.q. | New World Monkeys | 9 | 29 | 0 | 107 | 0 | 145 |
| 4.r. | Old World Monkeys | 9 | 69 | 52 | 315 | 9 | 454 |
| 4.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.u. | Quail | 0 | 0 | 0 | 20 | 0 | 20 |
| 4.v. | Other birds | 5 | 0 | 0 | 0 | 14916 | 14921 |
| 4.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.x. | Amphibians | 0 | 649 | 2018 | 1869 | 277 | 4813 |
| 4.y. | Fish | 0 | 0 | 0 | 32809 | 8331 | 41140 |
| 4.z. | TOTAL | 124130 | 352990 | 174867 | 452220 | 103314 | 1207521 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 EC legislation including European Pharmacopoeia (requirements) | 5.4 Member Country of Council of Europe (but not EC) legislation 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice | 5219 | 92021 | 0 | 500 | 428624 | 8082 | 534446 |
| 5.b. | Rats | 4608 | 13371 | 0 | 14938 | 1027 | 0 | 33944 |
| 5.c. | Guinea-Pigs | 0 | 9411 | 0 | 0 | 47947 | 6 | 57364 |
| 5.d. | Hamsters | 0 | 2254 | 0 | 0 | 0 | 0 | 2254 |
| 5.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.f. | Rabbits | 6 | 7978 | 0 | 0 | 56680 | 19 | 64683 |
| 5.g. | Cats | 0 | 458 | 0 | 0 | 0 | 0 | 458 |
| 5.h. | Dogs | 0 | 639 | 0 | 0 | 0 | 0 | 639 |
| 5.i. | Ferrets | 0 | 23 | 0 | 0 | 6 | 0 | 29 |
| 5.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 95 | 0 | 95 |
| 5.1. | Pigs | 0 | 1342 | 0 | 0 | 4 | 65 | 1411 |
| 5.m. | Goats | 0 | 0 | 0 | 0 | 77 | 0 | 77 |
| 5.n. | Sheep | 0 | 0 | 0 | 0 | 3062 | 0 | 3062 |
| 5.0. | Cattle | 0 | 11 | 0 | 0 | 1 | 0 | 12 |
| 5.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.q. | New World Monkeys | 0 | 35 | 0 | 0 | 0 | 0 | 35 |
| 5.r. | Old World Monkeys | 0 | 6 | 0 | 0 | 320 | 0 | 326 |
| 5.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.v. | Other birds | 0 | 37117 | 152 | 0 | 10657 | 0 | 47926 |
| 5.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.y. | Fish | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.z. | TOTAL | 9833 | 164666 | 152 | 15438 | 548500 | 8172 | 746761 |

## Examples:

5.2 - France is testing due to a UK (or FR) specific requirement 5.3 - UK is testing according to EC legislation 5.4 - Spain is testing due to a Hungarian requirement 5.5 - Sweden is testing due to a US specific requirement 5.6 - Germany is testing due to a Czech requirement (also an EC requirement)
columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol.
a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

 Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Regulatory requirements versus species

|  | 6.1 Species | 6.2 <br> National legislation specific to a single EC Member State <br> 1) | 6.3 EC legislation including European Pharmacopoeia (requirements) | 6.4 <br> Member Country of Council of Europe (but not EC) legislation <br> 2) | $\begin{gathered} \hline 6.5 \\ \text { Other legislation } \end{gathered}$ | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | 6.7 <br> No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice | 7381 | 17787 | 22 | 3586 | 34457 | 7803 | 71036 |
| 6.b. | Rats | 568 | 8729 | 0 | 5966 | 48339 | 6331 | 69933 |
| 6.c. | Guinea-Pigs | 414 | 9751 | 0 | 323 | 2107 | 527 | 13122 |
| 6.d. | Hamsters | 0 | 78 | 0 | 0 | 64 | 2 | 144 |
| 6.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.f. | Rabbits | 502 | 1631 | 0 | 1726 | 4669 | 1800 | 10328 |
| 6.g. | Cats | 0 | 24 | 0 | 0 | 0 | 0 | 24 |
| 6.h. | Dogs | 0 | 231 | 0 | 510 | 2547 | 139 | 3427 |
| 6.i. | Ferrets | 0 | 0 | 0 | 0 | 41 | 0 | 41 |
| 6.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.1. | Pigs | 31 | 187 | 0 | 132 | 512 | 140 | 1002 |
| 6.m. | Goats | 0 | 0 | 0 | 0 | 0 | 10 | 10 |
| 6.n. | Sheep | 0 | 0 | 0 | 0 | 10 | 0 | 10 |
| 6.0. | Cattle | 0 | 67 | 0 | 0 | 25 | 0 | 92 |
| 6.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.q. | New World Monkeys | 0 | 0 | 0 | 0 | 168 | 0 | 168 |
| 6.r. | Old World Monkeys | 0 | 253 | 0 | 488 | 1035 | 98 | 1874 |
| 6.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
|  | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.v. | Other birds | 629 | 98 | 0 | 0 | 35605 | 0 | 36332 |
| 6.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.x. | Amphibians | 500 | 0 | 0 | 0 | 0 | 0 | 500 |
| 6.y. | Fish | 0 | 3000 | 0 | 0 | 33 | 1915 | 4948 |
| 6.z. | TOTAL | 10025 | 41836 | 22 | 12731 | 129612 | 18765 | 212991 |
| Examples: 6.2 - France is testing due to a UK (or FR) specific requirement <br>  6.3 - UK is testing according to EC legislation <br>  6.4 - Spain is testing due to a Hungarian requirement <br>  6.5 - Sweden is testing due to a US specific requirement <br>  6.6 - Germany is testing due to a Czech requirement (also an EC <br>  requirement) |  |  |  | Example: a test required by French legislati ISO protocol must be coded as a entered into column 6.2 in the tab |  | imposing that the test tual test method, guid and carried out in Belgi (FR) legislative req bmitted by Belgium. | carried out and or protocol. ccording to an nent and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2Acute and sub-acute toxicity testing methods <br> (including limit test) |  |  | $\begin{array}{c\|} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{array}$ | 7.4 Skin sensitisatio n |  | 7.6 Sub- chronic and chronic toxicity | 7.7 Carcino- genicity | 7.8 <br> Developmental toxicity | 7.9 Muta- genicit $y$ | 7.10 Repro- ductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $7.12$ Other | $7.13$ <br> Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 2005 | 17724 | 9119 | 2493 | 8033 | 0 | 12909 | 5105 | 912 | 1001 | 315 | 0 | 11420 | 71036 |
| 7.b. | Rats | 1881 | 8642 | 5955 | 0 | 0 | 142 | 20645 | 6386 | 5301 | 4573 | 6247 | 0 | 10161 | 69933 |
| 7.c. | Guinea-Pigs | 0 | 92 | 282 | 1919 | 8239 | 0 | 352 | 0 | 0 | 0 | 0 | 0 | 2238 | 13122 |
| 7.d. | Hamsters | 0 | 64 | 0 | 0 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 78 | 144 |
| 7.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.f. | Rabbits | 0 | 15 | 1289 | 1494 | 0 | 1647 | 1026 | 0 | 2544 | 0 | 1254 | 0 | 1059 | 10328 |
| 7.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 24 | 24 |
| 7.h. | Dogs | 0 | 166 | 599 | 0 | 0 | 0 | 2429 | 0 | 0 | 0 | 0 | 0 | 233 | 3427 |
| 7.i. | Ferrets | 0 | 0 | 41 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 41 |
| 7.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.1. | Pigs | 0 | 49 | 0 | 0 | 0 | 0 | 262 | 0 | 89 | 0 | 0 | 0 | 602 | 1002 |
| 7.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 10 | 10 |
| 7.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 10 | 10 |
| 7.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 92 | 92 |
| 7.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.q. | New World Monkeys | 0 | 72 | 78 | 0 | 0 | 0 | 18 | 0 | 0 | 0 | 0 | 0 | 0 | 168 |
| 7.r. | Old World Monkeys | 0 | 0 | 259 | 0 | 0 | 33 | 1556 | 0 | 0 | 0 | 0 | 0 | 26 | 1874 |
| 7.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.v. | Other birds | 0 | 0 | 5087 | 0 | 0 | 0 | 98 | 0 | 0 | 0 | 0 | 0 | 31147 | 36332 |
| 7.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 500 | 500 |
| 7.y. | Fish | 1178 | 0 | 1000 | 0 | 0 | 0 | 2170 | 0 | 0 | 0 | 0 | 500 | 100 | 4948 |
| 7.z. | TOTAL | 5064 | 26824 | 23709 | 5906 | 16272 | 1822 | 41467 | 11491 | 8846 | 5574 | 7816 | 500 | 57700 | 212991 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products

| 8.1 <br> Products |  | 8.2 <br> Acute and sub-acute toxicity testing methods (including limit test) |  |  | 8.3Skinirritation | 8.4Skinsensitisation | 8.5Eyeirritation | 8.6 Sub- <br> chronic and chronic toxicity |  | 8.8 <br> Developmental toxicity | 8.9 <br> Mutagenicit <br> y | 8.10 <br> Reproductive toxicity | 8.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 8.12 \\ & \text { Other } \end{aligned}$ | $8.13$ <br> Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | $\begin{gathered} \hline 8.2 .1 . \\ \text { LD50, } \\ \text { LC50 } \end{gathered}$ | 8.2 .2 <br> Other lethal <br> methods | 8.2 .3 Non lethal clinical signs methods |  |  |  |  |  |  |  |  |  |  |  |
| 8.a. | Products/substances or devices for human medicine and dentistry and for veterinary medicine | 2016 | 13462 | 15447 | 1216 | 6197 | 792 | 18681 | 5623 | 3485 | 5016 | 5643 | 0 | 20038 | 97616 |
| 8.b. | Products/substances used or intended to be used mainly in agriculture | 2111 | 1683 | 1865 | 102 | 230 | 56 | 5896 | 1723 | 666 | 0 | 134 | 555 | 0 | 15021 |
| 8.c. | Products/substances used or intended to be used mainly in industry | 568 | 1080 | 1218 | 2455 | 972 | 119 | 9156 | 2488 | 873 | 2 | 0 | 0 | 34 | 18965 |
| 8.d. | Products/substances used or intended to be used mainly in the household | 0 | 18 | 0 | 36 | 133 | 67 | 0 | 0 | 0 | 0 | 0 | 0 | 45 | 299 |
| 8.e. | Products/substances used or intended to be used mainly as cosmetics or toiletries | 0 | 349 | 684 | 413 | 2222 | 281 | 966 | 0 | 368 | 213 | 0 | 0 | 0 | 5496 |
| 8.f. | Products/substances used or intended to be used mainly as additives in food for human consumption | 0 | 0 | 123 | 0 | 19 | 0 | 467 | 0 | 0 | 8 | 0 | 0 | 155 | 772 |
| 8.g. | Products/substances used or intended to be used mainly as additives in food for animal consumption | 0 | 0 | 185 | 0 | 0 | 0 | 0 | 24 | 0 | 0 | 0 | 0 | 31012 | 31221 |
| 8.h. | Potential or actual contaminants in the general environment which do not appear in other columns | 0 | 1289 | 287 | 0 | 0 | 0 | 1350 | 0 | 0 | 0 | 592 | 0 | 1044 | 4562 |
| 8.i. | Other toxicological or safety evaluations | 409 | 6943 | 1779 | 372 | 2096 | 367 | 18251 | 473 | 2298 | 2042 | 1180 | 0 | 2829 | 39039 |
| 8.j. | TOTAL | 5104 | 24824 | 21588 | 4594 | 11869 | 1682 | 54767 | 10331 | 7690 | 7281 | 7549 | 555 | 55157 | 212991 |

## HUNGARY

## Statistical data submitted

The statistical data have been submitted by the Ministry of Agriculture and Rural Development.

## Comments of the Hungarian authorities

2005 was the first year when Hungarian user establishments furnished data on the number of animals used for experimental and other scientific purposes in the harmonized eight table version of statistical reporting format. Furthermore, the data in this format were supplied on a voluntary basis. (The Hungarian law in force prescribes the use of the former 5-table version for statistical reporting.) This situation resulted in two consequences.

1. It is very difficult to compare the data of 2005 with those of the previous years when the former 5 -table version had been in use.
2. The novelty and unfamiliarity of the tables and lack of sufficient guidance on the meaning of the new columns may have had a negative impact on the accuracy and coherence of data. (For example, in Tables 5 and 6 the non mutually exclusive classification of regulatory requirements may have corrupted the precision of the breakdown of the total figures.)

All the above circumstances warrant caution in interpreting the data.

## Comments relating to the number of animals used

The total number of animals used for experimental and other scientific purposes in 2005 was 297.209 which represents $19 \%$ decrease compared to the same figure of 2004. (It is worth to note that the total number of animals had been relatively stable (365-377 thousand) in the period of 2001-2004). The decrease was $25 \%$ in the number of mice, $7 \%$ in case of rats, $28 \%$ for guinea-pigs, $66 \%$ in other rodents and $47 \%$ within birds. The number of used dogs and cats practically did not change. In contrast to the general decreasing tendency the use of fish more than doubled ( $+138 \%$ ) while the number of rabbits increased by $9 \%$.

Despite the considerable reduction in the number of rodents from year 2004 to year $2005(\sim 59.000$ animals) this group kept its proportion ( $86.4 \%$ ) within the total number of animals. Notable changes can be observed in the proportion of birds (a drop from $8.9 \%$ to $5.9 \%$ ) and that of fish (an increase from $1.1 \%$ to $3 \%$ ).

Due to the limiting conditions described above, however, it cannot be fairly judged whether these changes represent the beginning of a longer-term tendency or just reflect natural variation of the data.

When analysed by the purposes of the use of animals a slight increase can be observed in the fundamental biological research segment ( $3.7 \%$ ) while the number of animals substantially decreased in education $(51 \%)$, in diagnosis of disease and toxicological evaluations ( $32 \%$ each) and in the human and veterinary medicine field ( $21 \%$ ) including research, development, production and quality control. However, in absolute numbers the latter decrease (48.671) accounts for more than two thirds of the total decrease (68.008).

Compared to 2004 the proportion of fundamental research in overall usage augmented from $21 \%$ to $27 \%$ while that of medicine related use decreased from $62 \%$ to $60 \%$. Toxicological and safety investigations form the third largest part ( $10 \%$ ) of animal usage.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} \hline 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 <br> Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 138312 | 106993 | 29067 | 0 | 2252 |  |
| 1.b. | Rats (Rattus norvegicus) | 109479 | 102798 | 6681 | 0 | 0 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 8360 | 4688 | 3672 | 0 | 0 |  |
| 1.d. | Hamsters (Mesocricetus ) | 137 | 137 | 0 | 0 | 0 |  |
| 1.e. | Other Rodents (other Rodentia) | 381 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 9152 | 8640 | 0 | 0 | 512 | 0 |
| 1.g. | Cats (Felis catus) | 124 | 121 | 0 | 0 | 3 | 0 |
| 1.h. | Dogs (Canis familiaris) | 1206 | 966 | 104 | 0 | 136 | 0 |
| 1.i. | Ferrets (Mustela putorius furo) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.j. | Other Carnivores (other Carnivora) | 0 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 6 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 882 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 2 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 381 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 32 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. | New World Monkeys (Ceboidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 6 | 3 | 0 | 0 | 3 | 0 |
| 1.s. | Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. | Other Mammals (other Mammalia) | 0 |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 283 | 93 | 0 | 0 | 190 |  |
| 1.v. | Other birds (other Aves) | 17151 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 25 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 1709 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 9581 |  |  |  |  |  |
| 1.z. | TOTAL | 297209 |  |  |  |  |  |

 updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES
Purpose versus species

|  | $\begin{gathered} \hline 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 <br> Production and quality control of products and devices for veterinary medicine | 2.6 <br> Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 31950 | 67452 | 22717 | 0 | 8125 | 7050 | 988 | 30 | 138312 |
| 2.b. | Rats | 35834 | 64523 | 0 | 0 | 7625 | 0 | 1497 | 0 | 109479 |
| 2.c. | Guinea-Pigs | 771 | 2417 | 2562 | 0 | 2554 | 16 | 22 | 18 | 8360 |
| 2.d. | Hamsters | 137 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 137 |
| 2.e. | Other Rodents | 0 | 81 | 0 | 0 | 300 | 0 | 0 | 0 | 381 |
| 2.f. | Rabbits | 1146 | 3995 | 3011 | 24 | 702 | 105 | 167 | 2 | 9152 |
| 2.g. | Cats | 109 | 0 | 0 | 0 | 0 | 0 | 15 | 0 | 124 |
| 2.h. | Dogs | 273 | 92 | 0 | 0 | 633 | 0 | 208 | 0 | 1206 |
| 2.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 6 | 0 | 6 |
| 2.1. | Pigs | 173 | 261 | 0 | 0 | 26 | 55 | 82 | 285 | 882 |
| 2.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 2 |
| 2.n. | Sheep | 19 | 189 | 0 | 24 | 4 | 3 | 2 | 140 | 381 |
| 2.0. | Cattle | 6 | 12 | 0 | 0 | 8 | 0 | 6 | 0 | 32 |
| 2.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.r. | Old World Monkeys | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6 |
| 2.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.u. | Quail | 93 | 0 | 0 | 0 | 190 | 0 | 0 | 0 | 283 |
| 2.v. | Other birds | 3068 | 8070 | 132 | 3165 | 2244 | 360 | 109 | 3 | 17151 |
| 2.w. | Reptiles | 25 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 25 |
| 2.x. | Amphibians | 458 | 0 | 0 | 0 | 0 | 0 | 1251 | 0 | 1709 |
| 2.y. | Fish | 5365 | 0 | 0 | 0 | 3330 | 0 | 386 | 500 | 9581 |
| 2.z. | TOTAL | 79433 | 147092 | 28422 | 3213 | 25741 | 7589 | 4741 | 978 | 297209 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Products versus species

|  | $\begin{gathered} 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminents in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 2994 | 321 | 0 | 0 | 0 | 0 | 0 | 556 | 4254 | 8125 |
| 3.b. | Rats | 1556 | 1317 | 13 | 0 | 0 | 52 | 0 | 394 | 4293 | 7625 |
| 3.c. | Guinea-Pigs | 208 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 2344 | 2554 |
| 3.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.e. | Other Rodents | 300 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 300 |
| 3.f. | Rabbits | 55 | 18 | 0 | 0 | 0 | 0 | 0 | 0 | 629 | 702 |
| 3.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.h. | Dogs | 296 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 337 | 633 |
| 3.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.1. | Pigs | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 20 | 0 | 26 |
| 3.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.n. | Sheep | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 |
| 3.0. | Cattle | 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 8 |
| 3.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.u. | Quail | 0 | 190 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 190 |
| 3.v. | Other birds | 1444 | 0 | 0 | 0 | 0 | 0 | 0 | 800 | 0 | 2244 |
| 3.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.y. | Fish | 1000 | 430 | 0 | 0 | 0 | 0 | 0 | 1000 | 900 | 3330 |
| 3.z. | TOTAL | 7871 | 2278 | 13 | 0 | 0 | 52 | 0 | 2770 | 12757 | 25741 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES

|  | $\begin{gathered} 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 Studies specific to animal diseases | $\begin{gathered} \hline 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 2146 | 55622 | 7607 | 13195 | 5982 | 84552 |
| 4.b. | Rats | 3601 | 54589 | 1003 | 6056 | 15 | 65264 |
| 4.c. | Guinea-Pigs | 59 | 93 | 0 | 2167 | 301 | 2620 |
| 4.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.e. | Other Rodents | 0 | 75 | 0 | 6 | 0 | 81 |
| 4.f. | Rabbits | 350 | 2753 | 0 | 196 | 707 | 4006 |
| 4.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.h. | Dogs | 165 | 9 | 0 | 18 | 43 | 235 |
| 4.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.1. | Pigs | 61 | 0 | 0 | 14 | 189 | 264 |
| 4.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.n. | Sheep | 0 | 0 | 0 | 3 | 277 | 280 |
| 4.0. | Cattle | 0 | 0 | 0 | 0 | 20 | 20 |
| 4.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.v. | Other birds | 0 | 818 | 0 | 10 | 9906 | 10734 |
| 4.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.y. | Fish | 0 | 0 | 0 | 0 | 300 | 300 |
| 4.z. | TOTAL | 6382 | 113959 | 8610 | 21665 | 17740 | 168356 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE


TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 National legislation specific to a single EC Member State 1) | 6.3 EC legislation including European Pharmacopoeia (requirements) | 6.4 Member Country of Council of Europe (but not EC) legislation 2) | 6.5 Other legislation | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | 6.7 No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice | 2779 | 1839 | 148 | 0 | 3359 | 0 | 8125 |
| 6.b. | Rats | 945 | 900 | 646 | 0 | 5121 | 13 | 7625 |
| 6.c. | Guinea-Pigs | 0 | 946 | 0 | 0 | 1608 | 0 | 2554 |
| 6.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.e. | Other Rodents | 0 | 300 | 0 | 0 | 0 | 0 | 300 |
| 6.f. | Rabbits | 6 | 76 | 0 | 0 | 620 | 0 | 702 |
| 6.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.h. | Dogs | 242 | 60 | 0 | 0 | 331 | 0 | 633 |
| 6.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.1. | Pigs | 0 | 6 | 0 | 0 | 0 | 20 | 26 |
| 6.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.n. | Sheep | 0 | 4 | 0 | 0 | 0 | 0 | 4 |
| 6.0. | Cattle | 0 | 8 | 0 | 0 | 0 | 0 | 8 |
| 6.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.u. | Quail | 0 | 190 | 0 | 0 | 0 | 0 | 190 |
| 6.v. | Other birds | 0 | 1182 | 0 | 0 | 0 | 1062 | 2244 |
| 6.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| $6 . y$. | Fish | 1000 | 1430 | 0 | 0 | 900 | 0 | 3330 |
| 6.z. | TOTAL | 4972 | 6941 | 794 | 0 | 11939 | 1095 | 25741 |
| $\begin{array}{ll}\text { Examples: } & \text { 6.2 - France is testing due to a UK (or FR) specific requirement } \\ & \text { 6.3 - UK is testing according to EC legislation } \\ & \text { 6.4 - Spain is testing due to a Hungarian requirement } \\ & 6.5 \text { - Sweden is testing due to a US specific requirement } \\ & 6.6 \text { - Germany is testing due to a Czech requirement (also an EC }\end{array}$ |  |  |  | Example: a test required by French legislati ISO protocol must be coded as a entered into column 6.2 in the tab |  | imposing that the test tual test method, guide nd carried out in Belgi nal (FR) legislative req bmitted by Belgium. | carried out and or protocol. ccording to an ment and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2Acute and sub-acute toxicity testing methods <br> (including limit test) |  |  | 7.3 Skin irritation | 7.4 Skin sensitisatio n | 7.5 Eye irritation | 7.6 Sub- chronic and chronic toxicity | 7.7 <br> Carcinogenicity | $7.8$ <br> Developmental toxicity | 7.9 Muta- genicit $y$ | 7.10 <br> Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 7.12 \\ & \text { Other } \end{aligned}$ | $\begin{gathered} \hline 7.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 1781 | 427 | 2282 | 0 | 0 | 0 | 40 | 0 | 6 | 1068 | 0 | 0 | 2521 | 8125 |
| 7.b. | Rats | 160 | 529 | 2915 | 0 | 0 | 0 | 1129 | 47 | 6 | 13 | 773 | 0 | 2053 | 7625 |
| 7.c. | Guinea-Pigs | 368 | 0 | 419 | 0 | 1091 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 676 | 2554 |
| 7.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.e. | Other Rodents | 0 | 0 | 300 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 300 |
| 7.f. | Rabbits | 0 | 0 | 64 | 143 | 0 | 111 | 0 | 0 | 0 | 0 | 252 | 0 | 132 | 702 |
| 7.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.h. | Dogs | 0 | 0 | 311 | 0 | 0 | 0 | 200 | 0 | 0 | 0 | 0 | 0 | 122 | 633 |
| 7.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.1. | Pigs | 0 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 20 | 26 |
| 7.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.n. | Sheep | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 |
| 7.0. | Cattle | 0 | 0 | 8 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 8 |
| 7.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.u. | Quail | 0 | 110 | 80 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 190 |
| 7.v. | Other birds | 0 | 0 | 1008 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1236 | 2244 |
| 7.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.y. | Fish | 2330 | 0 | 900 | 0 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | 0 | 0 | 3330 |
| 7.z. | TOTAL | 4639 | 1066 | 8297 | 143 | 1091 | 111 | 1369 | 47 | 112 | 1081 | 1025 | 0 | 6760 | 25741 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products

| $8.1$ <br> Products |  | 8.2 <br> Acute and sub-acute toxicity testing methods (including limit test) |  |  | 8.3Skinirritation | 8.4Skinsensitisation | 8.5Eyeirritation | 8.6 Sub- <br> chronic and chronic toxicity | 8.7Carcino genicity | 8.8 <br> Developmental toxicity | $\begin{gathered} 8.9 \\ \text { Muta- } \\ \text { genicit } \\ y \end{gathered}$ | 8.10 Reproductive toxicity | 8.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 8.12 \\ & \text { Other } \end{aligned}$ | $\begin{aligned} & \hline 8.13 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | $\begin{aligned} & \hline \text { 8.2.1. } \\ & \text { LD50, } \\ & \text { LC50 } \end{aligned}$ | 8.2 .2 Other lethal methods | 8.2.3 <br> Non lethal clinical signs methods |  |  |  |  |  |  |  |  |  |  |  |
| 8.a. | Products/substances or devices for human medicine and dentistry and for veterinary medicine | 2778 | 24 | 2924 | 9 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | 0 | 2036 | 7871 |
| 8.b. | Products/substances used or intended to be used mainly in agriculture | 490 | 110 | 1425 | 12 | 0 | 111 | 80 | 0 | 0 | 0 | 0 | 0 | 158 | 2386 |
| 8.c. | Products/substances used or intended to be used mainly in industry | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 13 | 0 | 0 | 0 | 13 |
| 8.d. | Products/substances used or intended to be used mainly in the household | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8.e. | Products/substances used or intended to be used mainly as cosmetics or toiletries | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8.f. | Products/substances used or intended to be used mainly as additives in food for human consumption | 0 | 0 | 52 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 52 |
| 8.g. | Products/substances used or intended to be used mainly as additives in food for animal consumption | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8.h. | Potential or actual contaminants in the general environment which do not appear in other columns | 1000 | 0 | 760 | 0 | 0 | 0 | 0 | 47 | 12 | 0 | 131 | 0 | 820 | 2770 |
| 8.i. | Other toxicological or safety evaluations | 371 | 932 | 3136 | 122 | 1091 | 0 | 1289 | 0 | 0 | 1068 | 894 | 0 | 3746 | 12649 |
| 8.j. | TOTAL | 4639 | 1066 | 8297 | 143 | 1091 | 111 | 1369 | 47 | 112 | 1081 | 1025 | 0 | 6760 | 25741 |

## IRELAND

## Statistical data submitted

The statistical data for Ireland have been provided by the Department of Health and Children.

## Comments of Irish authorities

## General

-A total of 37,940 animals were used. This represents a reduction of $27 \%$ compared to 2002 (the last published figures).

- There were 539 valid licences during the period 1 January 2005-31 December 2005.
- 171 new licences were issued in 2005. This is an increase of $13 \%$ compared to 2002.
- Rodents accounted for $67 \%$ of all animals used.
- No primates were used. This was in accordance with Ireland's policy not to licence for the use of primates.
- Of the animals used, $39 \%(14,779)$ were bred in registered breeding establishments in Ireland.
- Universities and Colleges accounted for $76 \%(28,904)$ of all animals used in scientific procedures.
$-58 \%$ of all procedures $(21,929)$ used no anaesthesia (Certificate A). Certificate A is granted where the anaesthesia is considered to be more traumatic to the animal than the experiment itself or where anaesthesia is incompatible with the object of the experiment.
- $20 \%$ of animals $(7,557)$ were used in procedures involving anaesthesia with permitted recovery (Certificate B).
- 3,336 genetically modified animals were used in experimental activity. This represents approximately $9 \%$ of the total numbers used.


## Animals Used for Selected Purposes

$-9 \%$ of animals $(3,472)$ were involved in studies specific to animal diseases.

- Of the 382 pigs used in $2005,69 \%$ (263) were involved in studies on human and animal diseases.
- 119 cats were used, 64 of which were used in toxicology and other safety evaluations.
- 167 dogs were used, a reduction of $14 \%$ since 2002 .
- Education and training accounted for $2 \%$ (688) of the animals used.
- Of the 2,024 other birds, $95 \%(1,914)$ were used in behavioural studies.
- $82 \%$ (313) of the rabbits used were for the study of human cardiovascular diseases.
- 189 horses were used, an increase of 170 since $2002.91 \%$ of the horses used were for EC legislation including European Pharmacopoeia requirements. 117 of the horses were used with a Certificate A. Certificate A is granted where the anaesthesia is considered to be more traumatic to the animal than the experiment itself or where anaesthesia is incompatible with the object of the experiment.


## Toxicological and other Safety Evaluations

- No animals were used in the testing of cosmetic products.
- Toxicological and other safety evaluations accounted for $18 \%(6,869)$ of animals used.
$-98 \%$ of the animals used in toxicological and other safety evaluations were mice.
- 875 mice were used in $\mathrm{LD}_{50}$ and $\mathrm{LC}_{50}$ testing, a reduction of $33 \%$ since 2002.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} \hline 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} 1.2 \\ \text { Total } \end{gathered}$ | 1.3 <br> Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 17776 | 8767 | 8532 |  | 477 |  |
| 1.b. | Rats (Rattus norvegicus) | 7722 | 5733 | 1864 | 60 | 65 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 4 | 4 |  |  |  |  |
| 1.d. | Hamsters (Mesocricetus ) | 0 |  |  |  |  |  |
| 1.e. | Other Rodents (other Rodentia) | 0 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 379 | 19 | 360 |  |  |  |
| 1.g. | Cats (Felis catus) | 119 | 119 |  |  |  | 60 |
| 1.h. | Dogs (Canis familiaris) | 167 | 137 | 30 |  |  | 92 |
| 1.i. | Ferrets (Mustela putorius furo) | 0 |  |  |  |  |  |
| 1.j. | Other Carnivores (other Carnivora) | 0 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 189 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 382 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 0 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 601 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 2109 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 |  |  |  |  |  |
| 1.q. | New World Monkeys (Ceboidea) | 0 |  |  |  |  |  |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 0 |  |  |  |  |  |
| 1.s. | Apes (Hominoidea) | 0 |  |  |  |  |  |
| 1.t. | Other Mammals (other Mammalia) | 48 |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 0 |  |  |  |  |  |
| 1.v. | Other birds (other Aves) | 2024 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 0 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 0 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 6420 |  |  |  |  |  |
| 1.z. | TOTAL | 37940 |  |  |  |  |  |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 Biological studies of a fundamenta 1 nature | 2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6 ) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7Diagnosis of <br> disease | 2.8Education and <br> training | $\begin{gathered} 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 9922 | 603 |  |  | 6703 | 158 | 15 | 375 | 17776 |
| 2.b. | Rats | 6367 | 1209 |  |  |  | 76 | 26 | 44 | 7722 |
| 2.c. | Guinea-Pigs |  | 4 |  |  |  |  |  |  | 4 |
| 2.d. | Hamsters |  |  |  |  |  |  |  |  | 0 |
| 2.e. | Other Rodents |  |  |  |  |  |  |  |  | 0 |
| 2.f. | Rabbits | 61 | 304 |  |  |  |  |  | 14 | 379 |
| 2.g. | Cats |  | 10 | 45 |  | 64 |  |  |  | 119 |
| 2.h. | Dogs |  | 38 | 42 |  | 87 |  |  |  | 167 |
| 2.i. | Ferrets |  |  |  |  |  |  |  |  | 0 |
| 2.j. | Other Carnivores |  |  |  |  |  |  |  |  | 0 |
| 2.k. | Horses, donkeys and cross breds |  |  |  | 172 |  |  | 5 | 12 | 189 |
| 2.1. | Pigs | 130 | 123 |  |  |  | 10 | 99 | 20 | 382 |
| 2.m. | Goats |  |  |  |  |  |  |  |  | 0 |
| 2.n. | Sheep | 62 | 1 |  | 72 |  | 3 | 463 |  | 601 |
| 2.0. | Cattle | 1417 | 15 |  | 329 | 15 |  | 20 | 313 | 2109 |
| 2.p. | Prosimians |  |  |  |  |  |  |  |  | 0 |
| 2.q. | New World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.r. | Old World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.s. | Apes |  |  |  |  |  |  |  |  | 0 |
| 2.t. | Other Mammals | 4 | 44 |  |  |  |  |  |  | 48 |
| 2.u. | Quail |  |  |  |  |  |  |  |  | 0 |
| 2.v. | Other birds |  | 7 |  |  |  | 110 | 60 | 1847 | 2024 |
| 2.w. | Reptiles |  |  |  |  |  |  |  |  | 0 |
| 2.x. | Amphibians |  |  |  |  |  |  |  |  | 0 |
| 2.y. | Fish | 6408 |  |  |  |  |  |  | 12 | 6420 |
| 2.z. | TOTAL | 24371 | 2358 | 87 | 573 | 6869 | 357 | 688 | 2637 | 37940 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Products versus species

|  | $\begin{gathered} 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminents in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 150 |  |  |  |  |  |  |  | 6553 | 6703 |
| 3.b. | Rats |  |  |  |  |  |  |  |  |  | 0 |
| 3.c. | Guinea-Pigs |  |  |  |  |  |  |  |  |  | 0 |
| 3.d. | Hamsters |  |  |  |  |  |  |  |  |  | 0 |
| 3.e. | Other Rodents |  |  |  |  |  |  |  |  |  | 0 |
| 3.f. | Rabbits |  |  |  |  |  |  |  |  |  | 0 |
| 3.g. | Cats | 64 |  |  |  |  |  |  |  |  | 64 |
| 3.h. | Dogs | 87 |  |  |  |  |  |  |  |  | 87 |
| 3.i. | Ferrets |  |  |  |  |  |  |  |  |  | 0 |
| 3.j. | Other Carnivores |  |  |  |  |  |  |  |  |  | 0 |
| 3.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  | 0 |
| 3.1. | Pigs |  |  |  |  |  |  |  |  |  | 0 |
| 3.m. | Goats |  |  |  |  |  |  |  |  |  | 0 |
| 3.n. | Sheep |  |  |  |  |  |  |  |  |  | 0 |
| 3.0. | Cattle | 15 |  |  |  |  |  |  |  |  | 15 |
| 3.p. | Prosimians |  |  |  |  |  |  |  |  |  | 0 |
| 3.q. | New World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.s. | Apes |  |  |  |  |  |  |  |  |  | 0 |
| 3.t. | Other Mammals |  |  |  |  |  |  |  |  |  | 0 |
| 3.u. | Quail |  |  |  |  |  |  |  |  |  | 0 |
| 3.v. | Other birds |  |  |  |  |  |  |  |  |  | 0 |
| 3.w. | Reptiles |  |  |  |  |  |  |  |  |  | 0 |
| 3.x. | Amphibians |  |  |  |  |  |  |  |  |  | 0 |
| 3.y. | Fish |  |  |  |  |  |  |  |  |  | 0 |
| 3.z. | TOTAL | 316 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6553 | 6869 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES


TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 <br> National legislation specific to a single EC Member State <br> 1) | 5.3 EC legislation including European Pharmacopoeia (requirements) | 5.4 <br> Member Country of Council of Europe (but not EC) legislation <br> 2) | 5.5 Other legislation | 5.6 Any combination of 5.2/5.3/5.4/5.5 | 5.7 <br> No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice |  |  |  |  |  |  | 0 |
| 5.b. | Rats |  |  |  |  |  |  | 0 |
| 5.c. | Guinea-Pigs |  |  |  |  |  |  | 0 |
| 5.d. | Hamsters |  |  |  |  |  |  | 0 |
| 5.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 5.f. | Rabbits |  |  |  |  |  |  | 0 |
| 5.g. | Cats |  |  |  |  | 45 |  | 45 |
| 5.h. | Dogs |  |  |  |  | 42 |  | 42 |
| 5.i. | Ferrets |  |  |  |  |  |  | 0 |
| 5.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 5.k. | Horses, donkeys and cross breds |  | 172 |  |  |  |  | 172 |
| 5.1. | Pigs |  |  |  |  |  |  | 0 |
| 5.m | Goats |  |  |  |  |  |  | 0 |
| 5.n. | Sheep |  | 72 |  |  |  |  | 72 |
| 5.0. | Cattle |  | 286 |  |  |  | 43 | 329 |
| 5.p. | Prosimians |  |  |  |  |  |  | 0 |
| 5.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 5.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
| 5.s. | Apes |  |  |  |  |  |  | 0 |
|  | Other Mammals |  |  |  |  |  |  | 0 |
| 5.u. | Quail |  |  |  |  |  |  | 0 |
| 5.v. | Other birds |  |  |  |  |  |  | 0 |
| 5.w. | Reptiles |  |  |  |  |  |  | 0 |
| 5.x. | Amphibians |  |  |  |  |  |  | 0 |
| 5.y. | Fish |  |  |  |  |  |  | 0 |
| 5.z. | TOTAL |  | 530 | 0 | 0 | 87 | 43 | 660 |
| $\begin{array}{ll}\text { Examples: } & 5.2 \text { - France is testing due to a UK (or FR) specific requirement } \\ & 5.3 \text { - UK is testing according to EC legislation } \\ & 5.4 \text { - Spain is testing due to a Hungarian requirement } \\ & 5.5 \text { - Sweden is testing due to a US specific requirement } \\ & 5.6 \text { - Germany is testing due to a Czech requirement (also an EC }\end{array}$ |  |  |  | Example: a test required by French legisla ISO protocol must be coded as a entered into column 5.2 in the ta |  | imposing that the tes tual test method, guid d carried out in Belgi al (FR) legislative req bmitted by Belgium. | carried out and or protocol. ccording to an nent and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Regulatory requirements versus species

|  | 6.1 Species | 6.2 National legislation specific to a single EC Member State 1) | 6.3 EC legislation including European Pharmacopoeia (requirements) | 6.4 <br> Member Country of Council of Europe (but not EC) legislation <br> 2) | 6.5 Other legislation | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | 6.7 No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice |  | 5238 |  |  | 1465 |  | 6703 |
| 6.b. | Rats |  |  |  |  |  |  | 0 |
| 6.c. | Guinea-Pigs |  |  |  |  |  |  | 0 |
| 6.d. | Hamsters |  |  |  |  |  |  | 0 |
|  | Other Rodents |  |  |  |  |  |  | 0 |
| 6.f. | Rabbits |  |  |  |  |  |  | 0 |
| 6.g. | Cats | 64 |  |  |  |  |  | 64 |
| 6.h. | Dogs | 87 |  |  |  |  |  | 87 |
| 6.i. | Ferrets |  |  |  |  |  |  | 0 |
| 6.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 6.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 6.1. | Pigs |  |  |  |  |  |  | 0 |
| 6.m. | Goats |  |  |  |  |  |  | 0 |
|  | Sheep |  |  |  |  |  |  | 0 |
| 6.0. | Cattle |  |  |  |  |  | 15 | 15 |
| 6.p. | Prosimians |  |  |  |  |  |  | 0 |
| 6.q. | New World Monkeys |  |  |  |  |  |  | 0 |
|  | Old World Monkeys |  |  |  |  |  |  | 0 |
|  | Apes |  |  |  |  |  |  | 0 |
| 6.t. | Other Mammals |  |  |  |  |  |  | 0 |
| 6.u. | Quail |  |  |  |  |  |  | 0 |
|  | Other birds |  |  |  |  |  |  | 0 |
| 6.w. | Reptiles |  |  |  |  |  |  | 0 |
| 6.x. | Amphibians |  |  |  |  |  |  | 0 |
| 6.y. | Fish |  |  |  |  |  |  | 0 |
| 6.z. | TOTAL | 151 | 5238 | 0 | 0 | 1465 | 15 | 6869 |
| Examples: 6.2 - France is testing due to a UK (or FR) specific requirement <br>  6.3 - UK is testing according to EC legislation <br>  6.4 - Spain is testing due to a Hungarian requirement <br>  6.5 - Sweden is testing due to a US specific requirement <br>  6.6 - Germany is testing due to a Czech requirement (also an EC |  |  |  | Example: a test required by French legisla |  | imposing that the tes tual test method, guid d carried out in Belgi al (FR) legislative req bmitted by Belgium. | carried out and or protocol. ccording to an nent and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2Acute and sub-acute toxicity testing methods <br> (including limit test) |  |  | $\begin{array}{c\|} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{array}$ | 7.4 Skin sensitisatio n | 7.5 Eye irritation | 7.6 Sub- chronic and chronic toxicity | 7.7 Carcinogenicity | $7.8$ <br> Developmental toxicity | $\begin{gathered} 7.9 \\ \text { Muta- } \\ \text { genicit } \\ y \end{gathered}$ | 7.10 Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 7.12 \\ & \text { Other } \end{aligned}$ | $\begin{aligned} & \hline 7.13 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 875 | 4363 |  |  |  |  | 1465 |  |  |  |  |  |  | 6703 |
| 7.b. | Rats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.c. | Guinea-Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.e. | Other Rodents |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.f. | Rabbits |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.g. | Cats |  |  |  |  |  |  |  |  |  |  |  |  | 64 | 64 |
| 7.h. | Dogs |  |  |  |  |  |  |  |  |  |  |  |  | 87 | 87 |
| 7.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.1. | Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.m. | Goats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.n. | Sheep |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.0. | Cattle |  |  | 15 |  |  |  |  |  |  |  |  |  |  | 15 |
| 7.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.s. | Apes |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.u. | Quail |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.v. | Other birds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.y. | Fish |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.z. | TOTAL | 875 | 4363 | 15 | 0 | 0 | 0 | 1465 | 0 | 0 | 0 | 0 | 0 | 151 | 6869 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products


## ITALY

## Statistical data submitted

The statistical data have been submitted by the Ministry of Health - Department for public veterinary health food and animal safety, Directorate-General for animal health and veterinary medicines, Office X

## Comments of Italian authorities

The collected data are entered in the "harmonised EU statistical tables" agreed by the competent national authorities of the EU in 1997.

They generally confirm the downward trend in the total number of animals used in experiments, which has remained below the one million mark since 1999.
$\mathbf{9 3 . 6 1 \%}$ of the animals used were rodents and rabbits.
The tables also include data on animals used for in vitro studies (euthanised to remove organs, tissues and cells).
$\mathbf{4 4 . 0 8 \%}$ of the animals were used in basic biological studies.
$\mathbf{2 7 . 4 2 \%}$ of the animals were used in the research and development of products and devices for human medicine, dentistry and veterinary medicine.
$\mathbf{1 5 . 3 8 \%}$ of the animals were used in the production and quality control of products and devices for human medicine, dentistry and veterinary medicine.
$\mathbf{8 . 9 \%}$ of the animals were used in toxicological studies.
4.22\% of the animals were used for diagnosis of disease, education and other purposes.
$\mathbf{9 8 . 6 7 \%}$ of the animals were used to study human diseases, while $1.33 \%$ were used to study animal diseases.

Article 24 of Directive 86/609/EEC has allowed tighter rules to be introduced into Italian law, particularly regarding the use of non-human primates, cats and dogs, as may be seen from Article 3(2) of Legislative Decree 116/92, which states that "with regard to non-human primates, cats and dogs, the authorisation stipulated by Article 8(1)(b) is also required."

Special attention was also paid to the use of horses in experiments.
All in all, this means that horses, non-human primates, cats and dogs together account for $\mathbf{0 . 1 7 \%}$ of all animals used.

Cats are used in experiments in Italy only in investigations of diseases affecting cats themselves. Since 2003 no animals have been used to test finished cosmetic products.

## Signed:Prof. Sergio Papalia

## Director, Office

## TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

## Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 <br> Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from <br> Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 534614 | 516400 | 6073 | 97 | 12044 |  |
| 1.b. | Rats (Rattus norvegicus) | 279774 | 276681 | 2758 | 4 | 331 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 11533 | 6879 | 4613 | 15 | 26 |  |
| 1.d. | Hamsters (Mesocricetus ) | 1537 | 1473 | 0 | 0 | 64 |  |
| 1.e. | Other Rodents (other Rodentia) | 2303 |  |  | 0 | 0 |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 9916 | 9842 | 74 | 0 | 0 | 351 |
| 1.g. | Cats (Felis catus) | 30 | 0 | 30 | 0 | 0 | 0 |
| 1.h. | Dogs (Canis familiaris) | 1064 | 601 | 0 | 93 | 370 | 68 |
| 1.i. | Ferrets (Mustela putorius furo) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.j. | Other Carnivores (other Carnivora) | 0 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 63 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 2579 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 20 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 584 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 1174 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. | New World Monkeys (Ceboidea) | 17 | 12 | 5 | 0 | 0 | 87 |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 395 | 7 | 343 | 3 | 42 | 85 |
| 1.s. | Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. | Other Mammals (other Mammalia) | 68 |  |  |  | 0 | 0 |
| 1.u. | Quail (Coturnix coturnix) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.v. | Other birds (other Aves) | 31697 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 378 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 4636 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 14584 |  |  |  |  |  |
| 1.z. | TOTAL | 896966 |  |  |  |  |  |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

## Purpose versus species

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7Diagnosis of <br> disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 292138 | 146808 | 26561 | 4744 | 34518 | 24245 | 403 | 5197 | 534614 |
| 2.b. | Rats | 79546 | 83690 | 81993 | 170 | 30818 | 1115 | 317 | 2125 | 279774 |
| 2.c. | Guinea-Pigs | 1778 | 4040 | 3740 | 451 | 1444 | 53 | 15 | 12 | 11533 |
| 2.d. | Hamsters | 1092 | 76 | 0 | 0 | 57 | 312 | 0 | 0 | 1537 |
| 2.e. | Other Rodents | 400 | 1043 | 0 | 0 | 0 | 860 | 0 | 0 | 2303 |
| 2.f. | Rabbits | 1766 | 1228 | 4195 | 855 | 1626 | 38 | 0 | 208 | 9916 |
| 2.g. | Cats | 0 | 30 | 0 | 0 | 0 | 0 | 0 | 0 | 30 |
| 2.h. | Dogs | 12 | 59 | 0 | 0 | 993 | 0 | 0 | 0 | 1064 |
| 2.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.k. | Horses, donkeys and cross breds | 34 | 3 | 24 | 0 | 0 | 0 | 0 | 2 | 63 |
| 2.1. | Pigs | 758 | 405 | 18 | 71 | 333 | 0 | 249 | 745 | 2579 |
| 2.m. | Goats | 13 | 4 | 0 | 0 | 0 | 1 | 0 | 2 | 20 |
| 2.n. | Sheep | 187 | 257 | 51 | 75 | 14 | 0 | 0 | 0 | 584 |
| 2.0. | Cattle | 1024 | 62 | 1 | 73 | 0 | 10 | 0 | 4 | 1174 |
| 2.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.q. | New World Monkeys | 9 | 8 | 0 | 0 | 0 | 0 | 0 | 0 | 17 |
| 2.r. | Old World Monkeys | 20 | 11 | 37 | 0 | 327 | 0 | 0 | 0 | 395 |
| 2.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.t. | Other Mammals | 58 | 0 | 0 | 10 | 0 | 0 | 0 | 0 | 68 |
| 2.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.v. | Other birds | 6915 | 2519 | 15 | 14621 | 6102 | 3 | 0 | 1522 | 31697 |
| 2.w. | Reptiles | 348 | 0 | 0 | 0 | 0 | 0 | 0 | 30 | 378 |
| 2.x. | Amphibians | 4495 | 30 | 0 | 0 | 42 | 69 | 0 | 0 | 4636 |
| 2.y. | Fish | 4820 | 5674 | 0 | 310 | 3520 | 0 | 0 | 260 | 14584 |
| 2.z. | TOTAL | 395413 | 245947 | 116635 | 21380 | 79794 | 26706 | 984 | 10107 | 896966 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Products versus species

|  | 3.1 Species | 3.2 Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 Potential or actual contaminants in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 12523 | 69 | 290 | 0 | 0 | 390 | 182 | 2782 | 18282 | 34518 |
| 3.b. | Rats | 20550 | 288 | 2424 | 0 | 0 | 766 | 0 | 4830 | 1960 | 30818 |
| 3.c. | Guinea-Pigs | 959 | 70 | 397 | 0 | 0 | 0 | 0 | 0 | 18 | 1444 |
| 3.d. | Hamsters | 57 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 57 |
| 3.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.f. | Rabbits | 1479 | 0 | 129 | 0 | 0 | 0 | 0 | 0 | 18 | 1626 |
| 3.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.h. | Dogs | 929 | 0 | 64 | 0 | 0 | 0 | 0 | 0 | 0 | 993 |
| 3.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.1. | Pigs | 313 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 20 | 333 |
| 3.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.n. | Sheep | 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 14 |
| 3.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.r. | Old World Monkeys | 327 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 327 |
| 3.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.v. | Other birds | 6082 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 20 | 6102 |
| 3.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 42 | 42 |
| 3.y. | Fish | 255 | 0 | 0 | 0 | 0 | 0 | 0 | 3265 | 0 | 3520 |
| 3.z. | TOTAL | 43486 | 427 | 3304 | 0 | 0 | 1156 | 182 | 10877 | 20362 | 79794 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 Studies specific to animal diseases | $\begin{gathered} 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 13061 | 61492 | 113322 | 132766 | 4449 | 325090 |
| 4.b. | Rats | 7290 | 49905 | 9863 | 37583 | 196 | 104837 |
| 4.c. | Guinea-Pigs | 632 | 966 | 0 | 2891 | 189 | 4678 |
| 4.d. | Hamsters | 100 | 659 | 144 | 12 | 6 | 921 |
| 4.e. | Other Rodents | 0 | 986 | 0 | 196 | 727 | 1909 |
| 4.f. | Rabbits | 378 | 195 | 19 | 1030 | 120 | 1742 |
| 4.g. | Cats | 0 | 0 | 0 | 0 | 30 | 30 |
| 4.h. | Dogs | 6 | 141 | 268 | 49 | 6 | 470 |
| 4.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.1. | Pigs | 165 | 2 | 0 | 103 | 25 | 295 |
| 4.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.n. | Sheep | 11 | 0 | 40 | 18 | 32 | 101 |
| 4.0. | Cattle | 0 | 0 | 0 | 7 | 0 | 7 |
| 4.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.q. | New World Monkeys | 0 | 12 | 0 | 0 | 0 | 12 |
| 4.r. | Old World Monkeys | 0 | 3 | 125 | 6 | 0 | 134 |
| 4.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.v. | Other birds | 0 | 0 | 0 | 22 | 70 | 92 |
| 4.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.x. | Amphibians | 0 | 131 | 0 | 451 | 0 | 582 |
| 4.y. | Fish | 0 | 0 | 221 | 0 | 0 | 221 |
| 4.z. | TOTAL | 21643 | 114492 | 124002 | 175134 | 5850 | 441121 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 EC legislation including European Pharmacopoeia (requirements) | 5.4 Member Country of Council of Europe (but not EC) legislation 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice | 4176 | 7816 | 0 | 40 | 15405 | 3868 | 31305 |
| 5.b. | Rats | 425 | 1789 | 0 | 0 | 78237 | 1712 | 82163 |
| 5.c. | Guinea-Pigs | 1326 | 29 | 0 | 0 | 2630 | 206 | 4191 |
| 5.d. | Hamsters | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.f. | Rabbits | 1112 | 3297 | 0 | 0 | 460 | 181 | 5050 |
| 5.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.h. | Dogs | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.k. | Horses, donkeys and cross breds | 24 | 0 | 0 | 0 | 0 | 0 | 24 |
| 5.1. | Pigs | 50 | 39 | 0 | 0 | 0 | 0 | 89 |
| 5.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.n. | Sheep | 119 | 7 | 0 | 0 | 0 | 0 | 126 |
| 5.0. | Cattle | 57 | 17 | 0 | 0 | 0 | 0 | 74 |
| 5.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 37 | 0 | 37 |
| 5.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.t. | Other Mammals | 10 | 0 | 0 | 0 | 0 | 0 | 10 |
| 5.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.v. | Other birds | 1607 | 13029 | 0 | 0 | 0 | 0 | 14636 |
| 5.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.y. | Fish | 0 | 0 | 0 | 0 | 0 | 310 | 310 |
| 5.z. | TOTAL | 8906 | 26023 | 0 | 40 | 96769 | 6277 | 138015 |

Examples: 5.2 - France is testing due to a UK (or FR) specific requirement 5.3-UK is testing according to EC legislation 5.4 - Spain is testing due to a Hungarian requirement 5.5 - Sweden is testing due to a US specific requirement 5.6 - Germany is testing due to a Czech requirement (also an EC
columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

## TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 <br> National legislation <br> specific to a single EC <br> Member State <br> 1) | 6.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 6.4 <br> Member Country of Council <br> of Europe (but not EC) <br> legislation <br> 2) | 6.5 Other legislation | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | 6.7 No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice | 23592 | 6728 | 0 | 390 | 3259 | 549 | 34518 |
| 6.b. | Rats | 8821 | 8374 | 0 | 941 | 12359 | 323 | 30818 |
| 6.c. | Guinea-Pigs | 199 | 491 | 0 | 0 | 754 | 0 | 1444 |
| 6.d. | Hamsters | 0 | 48 | 0 | 0 | 9 | 0 | 57 |
| 6.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.f. | Rabbits | 110 | 555 | 0 | 0 | 874 | 87 | 1626 |
| 6.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.h. | Dogs | 137 | 272 | 0 | 0 | 584 | 0 | 993 |
| 6.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.1. | Pigs | 20 | 313 | 0 | 0 | 0 | 0 | 333 |
| 6.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.n. | Sheep | 2 | 12 | 0 | 0 | 0 | 0 | 14 |
| 6.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 327 | 0 | 327 |
| 6.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.v. | Other birds | 4840 | 1262 | 0 | 0 | 0 | 0 | 6102 |
| 6.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.x. | Amphibians | 42 | 0 | 0 | 0 | 0 | 0 | 42 |
| 6.y. | Fish | 3450 | 0 | 0 | 0 | 0 | 70 | 3520 |
| 6.z. | TOTAL | 41213 | 18055 | 0 | 1331 | 18166 | 1029 | 79794 |

Examples: 6.2 - France is testing due to a UK (or FR) specific requirement 6.3-UK is testing according to EC legislation 6.4 - Spain is testing due to a Hungarian requirement 6.5 - Sweden is testing due to a US specific requirement 6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

Note: columns 6.2-6.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 6.2 in the tables submitted by Belgium.

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2Acute and sub-acute toxicity testing methods(including limit test) |  |  | 7.3 Skin irritation | 7.4 Skin sensitisatio n | $\begin{gathered} \hline 7.5 \\ \text { Eye } \\ \text { irritation } \end{gathered}$ | 7.6 Sub- chronic and chronic toxicity | 7.7 <br> Carcinogenicity | $7.8$ <br> Developmental toxicity | 7.9 Muta- genicit $y$ | 7.10 Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 7.12 \\ & \text { Other } \end{aligned}$ | $\begin{gathered} \hline 7.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 1201 | 11332 | 6873 | 234 | 71 | 0 | 1298 | 3596 | 155 | 589 | 389 | 0 | 8780 | 34518 |
| 7.b. | Rats | 667 | 960 | 8144 | 0 | 0 | 0 | 7813 | 4807 | 1619 | 420 | 1352 | 0 | 5036 | 30818 |
| 7.c. | Guinea-Pigs | 0 | 0 | 37 | 97 | 1222 | 0 | 84 | 0 | 0 | 0 | 0 | 0 | 4 | 1444 |
| 7.d. | Hamsters | 0 | 0 | 48 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 9 | 57 |
| 7.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.f. | Rabbits | 0 | 0 | 400 | 147 | 5 | 38 | 64 | 0 | 514 | 0 | 264 | 0 | 194 | 1626 |
| 7.g. | Cats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.h. | Dogs | 0 | 4 | 285 | 0 | 0 | 0 | 657 | 0 | 0 | 0 | 0 | 0 | 47 | 993 |
| 7.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.1. | Pigs | 0 | 0 | 134 | 0 | 0 | 0 | 92 | 0 | 0 | 0 | 0 | 0 | 107 | 333 |
| 7.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.n. | Sheep | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 12 | 14 |
| 7.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.r. | Old World Monkeys | 0 | 1 | 93 | 0 | 0 | 0 | 158 | 0 | 0 | 0 | 0 | 0 | 75 | 327 |
| 7.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.v. | Other birds | 0 | 0 | 4840 | 1000 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 262 | 6102 |
| 7.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 42 | 0 | 0 | 0 | 0 | 42 |
| 7.y. | Fish | 2035 | 0 | 170 | 0 | 0 | 0 | 1100 | 0 | 0 | 0 | 0 | 215 | 0 | 3520 |
| 7.z. | TOTAL | 3903 | 12297 | 21026 | 1478 | 1298 | 38 | 11266 | 8403 | 2330 | 1009 | 2005 | 215 | 14526 | 79794 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products


## LATVIA

## Statistical data submitted

The statistical data have been submitted by the Ministry of Agriculture - State Food and veterinary service

## Comments of Latvian authorities

None

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} \hline 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} 1.2 \\ \text { Total } \end{gathered}$ | 1.3 <br> Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 10480 | 10480 |  |  |  |  |
| 1.b. | Rats (Rattus norvegicus) | 2376 | 2376 |  |  |  |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 297 | 297 |  |  |  |  |
| 1.d. | Hamsters (Mesocricetus ) | 0 |  |  |  |  |  |
| 1.e. | Other Rodents (other Rodentia) |  |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 166 | 166 |  |  |  |  |
| 1.g. | Cats (Felis catus) | 0 |  |  |  |  |  |
| 1.h. | Dogs (Canis familiaris) | 0 |  |  |  |  |  |
| 1.i. | Ferrets (Mustela putorius furo) | 0 |  |  |  |  |  |
| 1.j. | Other Carnivores (other Carnivora) |  |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) |  |  |  |  |  |  |
| 1.1. | Pigs (Sus) |  |  |  |  |  |  |
| 1.m | Goats (Capra) |  |  |  |  |  |  |
| 1.n. | Sheep (Ovis) |  |  |  |  |  |  |
| 1.0. | Cattle (Bos) |  |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 |  |  |  |  |  |
| 1.q. | New World Monkeys (Ceboidea) | 0 |  |  |  |  |  |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 0 |  |  |  |  |  |
| 1.s. | Apes (Hominoidea) | 0 |  |  |  |  |  |
| 1.t. | Other Mammals (other Mammalia) |  |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 0 |  |  |  |  |  |
| 1.v. | Other birds (other Aves) |  |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) |  |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) |  |  |  |  |  |  |
| 1.y. | Fish (Pisces) |  |  |  |  |  |  |
| 1.z. | TOTAL | 13319 | 13319 |  |  |  |  |

 updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 <br> Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8 Education and training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 2352 | 3068 | 2800 |  |  | 1494 | 766 |  | 10480 |
| 2.b. | Rats | 265 | 1105 | 613 |  | 90 | 126 | 177 |  | 2376 |
| 2.c. | Guinea-Pigs | 57 |  |  |  |  | 240 |  |  | 297 |
| 2.d. | Hamsters |  |  |  |  |  |  |  |  | 0 |
| 2.e. | Other Rodents |  |  |  |  |  |  |  |  | 0 |
| 2.f. | Rabbits | 121 |  |  |  |  | 45 |  |  | 166 |
| 2.g. | Cats |  |  |  |  |  |  |  |  | 0 |
| 2.h. | Dogs |  |  |  |  |  |  |  |  | 0 |
| 2.i. | Ferrets |  |  |  |  |  |  |  |  | 0 |
| 2.j. | Other Carnivores |  |  |  |  |  |  |  |  | 0 |
| 2.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  | 0 |
| 2.1. | Pigs |  |  |  |  |  |  |  |  | 0 |
| 2.m. | Goats |  |  |  |  |  |  |  |  | 0 |
| 2.n. | Sheep |  |  |  |  |  |  |  |  | 0 |
| 2.0. | Cattle |  |  |  |  |  |  |  |  | 0 |
| 2.p. | Prosimians |  |  |  |  |  |  |  |  | 0 |
| 2.q. | New World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.r. | Old World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.s. | Apes |  |  |  |  |  |  |  |  | 0 |
| 2.t. | Other Mammals |  |  |  |  |  |  |  |  | 0 |
| 2.u. | Quail |  |  |  |  |  |  |  |  | 0 |
| 2.v. | Other birds |  |  |  |  |  |  |  |  | 0 |
| 2.w. | Reptiles |  |  |  |  |  |  |  |  | 0 |
| 2.x. | Amphibians |  |  |  |  |  |  |  |  | 0 |
| 2.y. | Fish |  |  |  |  |  |  |  |  | 0 |
| 2.z. | TOTAL | 2795 | 4173 | 3413 | 0 | 90 | 1905 | 943 | 0 | 13319 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Products versus species

|  | $\begin{gathered} \hline 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminants in the general environment which do not appear in other columns | 3.10 <br> Other toxicological or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice |  |  |  |  |  |  |  |  |  | 0 |
| 3.b. | Rats |  |  |  |  |  |  |  |  | 90 | 90 |
| 3.c. | Guinea-Pigs |  |  |  |  |  |  |  |  |  | 0 |
| 3.d. | Hamsters |  |  |  |  |  |  |  |  |  | 0 |
| 3.e. | Other Rodents |  |  |  |  |  |  |  |  |  | 0 |
| 3.f. | Rabbits |  |  |  |  |  |  |  |  |  | 0 |
| 3.g. | Cats |  |  |  |  |  |  |  |  |  | 0 |
| 3.h. | Dogs |  |  |  |  |  |  |  |  |  | 0 |
| 3.i. | Ferrets |  |  |  |  |  |  |  |  |  | 0 |
| 3.j. | Other Carnivores |  |  |  |  |  |  |  |  |  | 0 |
| 3.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  | 0 |
| 3.1. | Pigs |  |  |  |  |  |  |  |  |  | 0 |
| 3.m. | Goats |  |  |  |  |  |  |  |  |  | 0 |
| 3.n. | Sheep |  |  |  |  |  |  |  |  |  | 0 |
| 3.0. | Cattle |  |  |  |  |  |  |  |  |  | 0 |
| 3.p. | Prosimians |  |  |  |  |  |  |  |  |  | 0 |
| 3.q. | New World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.s. | Apes |  |  |  |  |  |  |  |  |  | 0 |
| 3.t. | Other Mammals |  |  |  |  |  |  |  |  |  | 0 |
| 3.u. | Quail |  |  |  |  |  |  |  |  |  | 0 |
| 3.v. | Other birds |  |  |  |  |  |  |  |  |  | 0 |
| 3.w. | Reptiles |  |  |  |  |  |  |  |  |  | 0 |
| 3.x. | Amphibians |  |  |  |  |  |  |  |  |  | 0 |
| 3.y. | Fish |  |  |  |  |  |  |  |  |  | 0 |
| 3.z. | TOTAL | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 90 | 90 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES


TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 <br> National legislation <br> specific to a single EC <br> Member State <br> 1) | 6.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 6.4 Member Country of Council of Europe (but not EC) legislation 2) | 6.5 Other legislation | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | 6.7 No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice |  |  |  |  |  |  | 0 |
| 6.b. | Rats |  |  |  |  |  | 90 | 90 |
| 6.c. | Guinea-Pigs |  |  |  |  |  |  | 0 |
| 6.d. | Hamsters |  |  |  |  |  |  | 0 |
| 6.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 6.f. | Rabbits |  |  |  |  |  |  | 0 |
| 6.g. | Cats |  |  |  |  |  |  | 0 |
| 6.h. | Dogs |  |  |  |  |  |  | 0 |
| 6.i. | Ferrets |  |  |  |  |  |  | 0 |
| 6.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 6.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 6.1. | Pigs |  |  |  |  |  |  | 0 |
| 6.m. | Goats |  |  |  |  |  |  | 0 |
| 6.n. | Sheep |  |  |  |  |  |  | 0 |
| 6.0. | Cattle |  |  |  |  |  |  | 0 |
| 6.p. | Prosimians |  |  |  |  |  |  | 0 |
| 6.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 6.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
| 6.s. | Apes |  |  |  |  |  |  | 0 |
| 6.t. | Other Mammals |  |  |  |  |  |  | 0 |
| 6.u. | Quail |  |  |  |  |  |  | 0 |
| 6.v. | Other birds |  |  |  |  |  |  | 0 |
| 6.w. | Reptiles |  |  |  |  |  |  | 0 |
| 6.x. | Amphibians |  |  |  |  |  |  | 0 |
| 6.y. | Fish |  |  |  |  |  |  | 0 |
| 6.z. | TOTAL | 0 | 0 | 0 | 0 | 0 | 90 | 90 |

Ex
6.2 - France is testing due to a UK (or FR) specific requirement 6.3 - UK is testing according to EC legislation 6.4 - Spain is testing due to a Hungarian requirement 6.5 - Sweden is testing due to a US specific requirement 6.6 - Germany is testing due to a Czech requirement (also an EC requirement)

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

|  |  | 7.2 <br> Acute and sub-acute toxicity testing methods (including limit test) |  |  | 7.3 Skin irritation | 7.4 Skin sensitisatio n | 7.5 Eye irritation | 7.6 Sub- chronic and chronic toxicity | 7.7 Carcinogenicity | 7.8 <br> Developmental toxicity | $\begin{gathered} \hline 7.9 \\ \text { Muta- } \\ \text { genicit } \\ y \end{gathered}$ | 7.10 Repro- ductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 7.12 \\ & \text { Other } \end{aligned}$ | $\begin{gathered} \hline 7.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.b. | Rats |  |  |  |  |  |  |  |  |  |  | 90 |  |  | 90 |
| 7.c. | Guinea-Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.e. | Other Rodents |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.f. | Rabbits |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.g. | Cats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.h. | Dogs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.1. | Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.m. | Goats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.n. | Sheep |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.0. | Cattle |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.s. | Apes |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.u. | Quail |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.v. | Other birds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.y. | Fish |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.z. | TOTAL | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 90 | 0 | 0 | 90 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products


## LITHUANIA

## Statistical data submitted

The statistical data have been submitted by the State Food and Veterinary service Animal welfare department - Siesiku 19 LT-2010 Vilnius

## Comments of Lithuanian authorities

None

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} \hline 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} 1.2 \\ \text { Total } \end{gathered}$ | 1.3 <br> Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6 <br> Animals coming from other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 5116 | 5116 |  |  |  |  |
| 1.b. | Rats (Rattus norvegicus) | 493 | 493 |  |  |  |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 0 |  |  |  |  |  |
| 1.d. | Hamsters (Mesocricetus ) | 0 |  |  |  |  |  |
| 1.e. | Other Rodents (other Rodentia) |  |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 158 | 158 |  |  |  |  |
| 1.g. | Cats (Felis catus) | 0 |  |  |  |  |  |
| 1.h. | Dogs (Canis familiaris) | 0 |  |  |  |  |  |
| 1.i. | Ferrets (Mustela putorius furo) | 0 |  |  |  |  |  |
| 1.j. | Other Carnivores (other Carnivora) |  |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) |  |  |  |  |  |  |
| 1.1. | Pigs (Sus) |  |  |  |  |  |  |
| 1.m | Goats (Capra) |  |  |  |  |  |  |
| 1.n. | Sheep (Ovis) |  |  |  |  |  |  |
| 1.0. | Cattle (Bos) |  |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 |  |  |  |  |  |
| 1.q. | New World Monkeys (Ceboidea) | 0 |  |  |  |  |  |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 0 |  |  |  |  |  |
| 1.s. | Apes (Hominoidea) | 0 |  |  |  |  |  |
| 1.t. | Other Mammals (other Mammalia) |  |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 0 |  |  |  |  |  |
| 1.v. | Other birds (other Aves) |  |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) |  |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) |  |  |  |  |  |  |
| 1.y. | Fish (Pisces) |  |  |  |  |  |  |
| 1.z. | TOTAL | 5767 |  |  |  |  |  |

 updated list of those countries has to be used when filling in this column.

## Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES Purpose versus species

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7Diagnosis of <br> disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 1773 |  |  |  | 330 | 2583 | 430 |  | 5116 |
| 2.b. | Rats | 323 |  |  |  | 120 |  | 50 |  | 493 |
| 2.c. | Guinea-Pigs |  |  |  |  |  |  |  |  | 0 |
| 2.d. | Hamsters |  |  |  |  |  |  |  |  | 0 |
| 2.e. | Other Rodents |  |  |  |  |  |  |  |  | 0 |
| 2.f. | Rabbits | 96 |  |  |  | 62 |  |  |  | 158 |
| 2.g. | Cats |  |  |  |  |  |  |  |  | 0 |
| 2.h. | Dogs |  |  |  |  |  |  |  |  | 0 |
| 2.i. | Ferrets |  |  |  |  |  |  |  |  | 0 |
| 2.j. | Other Carnivores |  |  |  |  |  |  |  |  | 0 |
| 2.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  | 0 |
| 2.1. | Pigs |  |  |  |  |  |  |  |  | 0 |
| 2.m. | Goats |  |  |  |  |  |  |  |  | 0 |
| 2.n. | Sheep |  |  |  |  |  |  |  |  | 0 |
| 2.o. | Cattle |  |  |  |  |  |  |  |  | 0 |
| 2.p. | Prosimians |  |  |  |  |  |  |  |  | 0 |
| 2.q. | New World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.r. | Old World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.s. | Apes |  |  |  |  |  |  |  |  | 0 |
| 2.t. | Other Mammals |  |  |  |  |  |  |  |  | 0 |
| 2.u. | Quail |  |  |  |  |  |  |  |  | 0 |
| 2.v. | Other birds |  |  |  |  |  |  |  |  | 0 |
| 2.w. | Reptiles |  |  |  |  |  |  |  |  | 0 |
| 2.x. | Amphibians |  |  |  |  |  |  |  |  | 0 |
| 2.y. | Fish |  |  |  |  |  |  |  |  | 0 |
| 2.z. | TOTAL | 2192 | 0 | 0 | 0 | 512 | 2583 | 480 | 0 | 5767 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Products versus species

|  | $\begin{gathered} \hline 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminants in the general environment which do not appear in other columns | 3.10 <br> Other toxicological or safety evaluations | $\begin{gathered} \hline 3.11 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice |  | 330 |  |  |  |  |  |  |  | 330 |
| 3.b. | Rats |  | 120 |  |  |  |  |  |  |  | 120 |
| 3.c. | Guinea-Pigs |  |  |  |  |  |  |  |  |  | 0 |
| 3.d. | Hamsters |  |  |  |  |  |  |  |  |  | 0 |
| 3.e. | Other Rodents |  |  |  |  |  |  |  |  |  | 0 |
| 3.f. | Rabbits | 62 |  |  |  |  |  |  |  |  | 62 |
| 3.g. | Cats |  |  |  |  |  |  |  |  |  | 0 |
| 3.h. | Dogs |  |  |  |  |  |  |  |  |  | 0 |
| 3.i. | Ferrets |  |  |  |  |  |  |  |  |  | 0 |
| 3.j. | Other Carnivores |  |  |  |  |  |  |  |  |  | 0 |
| 3.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  | 0 |
| 3.1. | Pigs |  |  |  |  |  |  |  |  |  | 0 |
| 3.m. | Goats |  |  |  |  |  |  |  |  |  | 0 |
| 3.n. | Sheep |  |  |  |  |  |  |  |  |  | 0 |
| 3.0. | Cattle |  |  |  |  |  |  |  |  |  | 0 |
| 3.p. | Prosimians |  |  |  |  |  |  |  |  |  | 0 |
| 3.q. | New World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.s. | Apes |  |  |  |  |  |  |  |  |  | 0 |
| 3.t. | Other Mammals |  |  |  |  |  |  |  |  |  | 0 |
| 3.u. | Quail |  |  |  |  |  |  |  |  |  | 0 |
| 3.v. | Other birds |  |  |  |  |  |  |  |  |  | 0 |
| 3.w. | Reptiles |  |  |  |  |  |  |  |  |  | 0 |
| 3.x. | Amphibians |  |  |  |  |  |  |  |  |  | 0 |
| 3.y. | Fish |  |  |  |  |  |  |  |  |  | 0 |
| 3.z. | TOTAL | 62 | 450 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 512 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES


TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 5.4 <br> Member Country of Council <br> of Europe (but not EC) <br> legislation <br> 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice |  |  |  |  |  |  | 0 |
| 5.b. | Rats |  |  |  |  |  |  | 0 |
| 5.c. | Guinea-Pigs |  |  |  |  |  |  | 0 |
| 5.d. | Hamsters |  |  |  |  |  |  | 0 |
| 5.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 5.f. | Rabbits |  |  |  |  |  |  | 0 |
| 5.g. | Cats |  |  |  |  |  |  | 0 |
| 5.h. | Dogs |  |  |  |  |  |  | 0 |
| 5.i. | Ferrets |  |  |  |  |  |  | 0 |
| 5.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 5.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 5.1. | Pigs |  |  |  |  |  |  | 0 |
| 5.m | Goats |  |  |  |  |  |  | 0 |
| 5.n. | Sheep |  |  |  |  |  |  | 0 |
| 5.o. | Cattle |  |  |  |  |  |  | 0 |
| 5.p. | Prosimians |  |  |  |  |  |  | 0 |
| 5.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 5.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
| 5.s. | Apes |  |  |  |  |  |  | 0 |
| 5.t. | Other Mammals |  |  |  |  |  |  | 0 |
| 5.u. | Quail |  |  |  |  |  |  | 0 |
| 5.v. | Other birds |  |  |  |  |  |  | 0 |
| 5.w | Reptiles |  |  |  |  |  |  | 0 |
| 5.x. | Amphibians |  |  |  |  |  |  | 0 |
| 5.y. | Fish |  |  |  |  |  |  | 0 |
| 5.z. | TOTAL | 0 |  | 0 | 0 | 0 | 0 | 0 |
| Examples: 5.2 - France is te <br>  $5.3-$ UK is testin |  | a UK (or FR) specif to EC legislation a Hungarian require o a US specific requi due to a Czech req | equirement <br> ent <br> ment (also an E | Note: columns $5.2-$ <br>  not to the bod <br> Example: a test require <br>  ISO protocol <br>  entered into | which has issued y French legisla st be coded as a umn 5.2 in the ta | imposing that the test tual test method, guide d carried out in Belgiu al (FR) legislative requ bmitted by Belgium. | carried out and or protocol. ccording to an nent and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 National legislation specific to a single EC Member State 1) | 6.3 EC legislation including European Pharmacopoeia (requirements) | 6.4 Member Country of Council of Europe (but not EC) legislation 2) | 6.5 Other legislation | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | $\begin{gathered} \hline 6.7 \\ \text { No regulatory } \\ \text { requirements } \end{gathered}$ | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice |  | 330 |  |  |  |  | 330 |
| 6.b. | Rats |  | 120 |  |  |  |  | 120 |
| 6.c. | Guinea-Pigs |  |  |  |  |  |  | 0 |
| 6.d. | Hamsters |  |  |  |  |  |  | 0 |
| 6.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 6.f. | Rabbits |  | 62 |  |  |  |  | 62 |
| 6.g. | Cats |  |  |  |  |  |  | 0 |
| 6.h. | Dogs |  |  |  |  |  |  | 0 |
| 6.i. | Ferrets |  |  |  |  |  |  | 0 |
| 6.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 6.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 6.1. | Pigs |  |  |  |  |  |  | 0 |
| 6.m | Goats |  |  |  |  |  |  | 0 |
| 6.n. | Sheep |  |  |  |  |  |  | 0 |
| 6.0. | Cattle |  |  |  |  |  |  | 0 |
| 6.p. | Prosimians |  |  |  |  |  |  | 0 |
| 6.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 6.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
| 6.s. | Apes |  |  |  |  |  |  | 0 |
| 6.t. | Other Mammals |  |  |  |  |  |  | 0 |
| 6.u. | Quail |  |  |  |  |  |  | 0 |
| 6.v. | Other birds |  |  |  |  |  |  | 0 |
| 6.w | Reptiles |  |  |  |  |  |  | 0 |
| 6.x. | Amphibians |  |  |  |  |  |  | 0 |
| 6.y. | Fish |  |  |  |  |  |  | 0 |
| 6.z. | TOTAL | 0 | 512 | 0 | 0 | 0 | 0 | 512 |
| Examples: 6.2 - France is te <br>  6.3 - UK is testing <br>  6.4 - Spain is tes <br>  6.5 - Sweden is t <br>  6.6 - Germany |  | a UK (or FR) specif to EC legislation Hungarian require o a US specific requi due to a Czech req | quirement <br> ent <br> ment (also an EC | Note:  <br>  columns $6.2-$ <br> not to the bod  <br>  a test require <br>  ISO protocol <br>  entered into | which has issued by French legislat ust be coded as a umn 6.2 in the tab | imposing that the test tual test method, guide d carried out in Belgit al (FR) legislative requ bmitted by Belgium. | carried out and or protocol. according to an ment and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

|  | 7.1 Species | Acute and | 7.2-acute toxicitycluding limit7.2.2Other lethal <br> methods | sting methods <br> 7.2.3 <br> Non lethal <br> clinical signs methods | 7.3 Skin irritation | 7.4 Skin sensitisatio n | 7.5 Eye irritation | 7.6 <br> Subchronic and chronic toxicity |  | 7.8 <br> Developmental toxicity | 7.9 <br> Mutagenicit y | 7.10 <br> Repro- <br> ductive <br> toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $7.12$ Other | $\begin{gathered} \hline 7.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice |  |  | 100 |  |  |  |  |  |  |  |  |  | 230 | 330 |
| 7.b. | Rats |  |  | 60 |  |  |  |  |  |  |  |  |  | 60 | 120 |
| 7.c. | Guinea-Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.e. | Other Rodents |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.f. | Rabbits |  |  |  |  |  |  |  |  |  |  |  |  | 62 | 62 |
| 7.g. | Cats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.h. | Dogs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.1. | Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.m. | Goats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.n. | Sheep |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.0. | Cattle |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.s. | Apes |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.u. | Quail |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.v. | Other birds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.y. | Fish |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.z. | TOTAL | 0 | 0 | 160 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 352 | 512 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products


## LUXEMBOURG

## Statistical data submitted

The statistical data have been submitted by the "Ministère de l'Agriculture, de la viticulture et du developpement rural. Administration des Services Vétérinaires" (Ministry of Agriculture, viticulture and rural development. Administration of Veterinary Services)

## Comments of Luxembourg authorities

Comments on statistical data on the use of laboratory animals in the Grand Duchy of Luxembourg in 2005

To DG Environment D.1.

- 2 experimentation projects were registered in Luxembourg in 2005 compared to 1 project in 2004.
- In comparison with 2004, a $62 \%$ decrease in the number of laboratory animals used has been recorded ( 280 more mice, but 500 fewer chicks and 1800 fewer cotton rats).
- Responsibility for monitoring animal welfare lies with a veterinary inspector, who carries out at least 2 inspections per year per requested experimentation project.
- Detection infrastructure and the handling of laboratory animals comply with animal welfare requirements.
- The experiments are intended for:
a) an immunological study of the protective efficiency and the antigenicity of antigens to improve vaccination strategies and diagnostic procedures for specific diseases;
b) projects relating to immunology and immunodeficiency.

Director of the Veterinary
Services Administration
Dr Arthur Besch

## Remark:

Please note that only relevant EU tables containing data are included in this report. No uses of animals were reported in Tables 3-8.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | $\begin{gathered} \hline 1.7 \\ \text { Re-used animals } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 3280 | 3280 |  |  |  |  |
| 1.b. | Rats (Rattus norvegicus) | 720 | 720 |  |  |  |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 100 | 100 |  |  |  |  |
| 1.d. | Hamsters (Mesocricetus ) | 0 |  |  |  |  |  |
| 1.e. | Other Rodents (other Rodentia) |  |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 20 | 20 |  |  |  |  |
| 1.g. | Cats (Felis catus) | 0 |  |  |  |  |  |
| 1.h. | Dogs (Canis familiaris) | 0 |  |  |  |  |  |
| 1.i. | Ferrets (Mustela putorius furo) | 0 |  |  |  |  |  |
| 1.j. | Other Carnivores (other Carnivora) |  |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) |  |  |  |  |  |  |
| 1.1. | Pigs (Sus) |  |  |  |  |  |  |
| 1.m. | Goats (Capra) |  |  |  |  |  |  |
| 1.n. | Sheep (Ovis) |  |  |  |  |  |  |
| 1.0. | Cattle (Bos) |  |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 |  |  |  |  |  |
| 1.q. | New World Monkeys (Ceboidea) | 0 |  |  |  |  |  |
|  | Old World Monkeys (Cercopithecoidea) | 0 |  |  |  |  |  |
| 1.s. | Apes (Hominoidea) | 0 |  |  |  |  |  |
| 1.t. | Other Mammals (other Mammalia) |  |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 0 |  |  |  |  |  |
| 1.v. | Other birds (other Aves) |  |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) |  |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) |  |  |  |  |  |  |
| 1.y. | Fish (Pisces) |  |  |  |  |  |  |
| 1.z. | TOTAL | 4120 | 4120 |  |  |  |  |

 updated list of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 <br> Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 280 | 3000 |  |  |  |  |  |  | 3280 |
| 2.b. | Rats | 320 | 400 |  |  |  |  |  |  | 720 |
| 2.c. | Guinea-Pigs |  | 100 |  |  |  |  |  |  | 100 |
| 2.d. | Hamsters |  |  |  |  |  |  |  |  | 0 |
| 2.e. | Other Rodents |  |  |  |  |  |  |  |  | 0 |
| 2.f. | Rabbits |  | 20 |  |  |  |  |  |  | 20 |
| 2.g. | Cats |  |  |  |  |  |  |  |  | 0 |
| 2.h. | Dogs |  |  |  |  |  |  |  |  | 0 |
| 2.i. | Ferrets |  |  |  |  |  |  |  |  | 0 |
| 2.j. | Other Carnivores |  |  |  |  |  |  |  |  | 0 |
| 2.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  | 0 |
| 2.1. | Pigs |  |  |  |  |  |  |  |  | 0 |
| 2.m. | Goats |  |  |  |  |  |  |  |  | 0 |
| 2.n. | Sheep |  |  |  |  |  |  |  |  | 0 |
| 2.0. | Cattle |  |  |  |  |  |  |  |  | 0 |
| 2.p. | Prosimians |  |  |  |  |  |  |  |  | 0 |
| 2.q. | New World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.r. | Old World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.s. | Apes |  |  |  |  |  |  |  |  | 0 |
| 2.t. | Other Mammals |  |  |  |  |  |  |  |  | 0 |
| 2.u. | Quail |  |  |  |  |  |  |  |  | 0 |
| 2.v. | Other birds |  |  |  |  |  |  |  |  | 0 |
| 2.w. | Reptiles |  |  |  |  |  |  |  |  | 0 |
| 2.x. | Amphibians |  |  |  |  |  |  |  |  | 0 |
| 2.y. | Fish |  |  |  |  |  |  |  |  | 0 |
| 2.z. | TOTAL | 600 | 3520 | 0 | 0 | 0 | 0 | 0 | 0 | 4120 |

## MALTA

No animals were used in Malta in 2005 for experimental or other scientific purposes.

## THE NETHERLANDS

## Statistical data submitted

The statistical data have been submitted by the "Keuringsdienst van Waren, Ministerie voor Volksgezondheid, Welzijn en Sport" (Inspectorate for Goods, Ministry for Public Health, Welfare and Sports

## Comments of the Dutch authorities

## National vs EU statistics

Since the first national report was published in 1978 the total number of animal experiments has never been as low as in 2005. After a faster decline the first 10-15 years the decrease slowed down the last 10 years. However the overall tendency still seems to be decreasing though in a slower pace.

The national statistics are published annually including the eight tables constructed in accordance with the EU system. The latest reports can be found at www.vwa.nl. The Dutch national statistics differ slightly form the Dutch EU-contribution. The numbers in the national statistics are higher due to the following:

1. In addition to the EU statistics, killing animals solely for harvesting tissues or organs is considered to be an experiment and contributes to the statistics. In 2005 a total number of 55.144 animals (i.e. $7 \%$ of the total number of animals used) were killed for this purpose, without any procedures or techniques connected with the experiment performed on them before their death.
2. Furthermore the Dutch statistics are based on the number of experiments performed and not so much on the number of animals involved. Therefore re-use is included as well. It clearly influences the statistics, hence each and every time the animal was used will contribute to the total number of experiments. In 200528.717 animal experiments were conducted on animals that had already been used. These animals were not included in the EU statistics.

The national statistics include 19 tables relating species to different topics. Like e.g. origin of the animal, type of experiment, severity score, mandatory testing, anaesthesia, pain alleviation, etc. Furthermore 14 tables on type of experiment versus species and their origin, safety testing and special techniques, etc are published. Special tables are made per university (hospital and academia alike) 15 in total and 2 tables on research performed for the ministry of Defence.

Severity scoring
All animal experiments have to go through a procedure of ethical reviewing prior to the start of the experiment. Part of the ethical reviewing is assessing by the responsible researcher, proposed expected severity score. During the experiment the animals are closely watched also to assess the actually experienced discomfort, harm, distress, etc. The experienced severity score is the one that is registered. The Dutch law recognises 6 severity bands:

- minor ( $35.5 \%$ of the experiments in 2005)
- minor/moderate ( $29.2 \%$ of the experiments in 2005)
- moderate ( $22.0 \%$ of the experiments in 2005)
- moderate/severe ( $8.8 \%$ of the experiments in 2005)
- severe ( $4.5 \%$ of the experiments in 2005)
- very severe ( $0.1 \%$ of the experiments in 2005)

Primates
In 2005327 primates were used ( 50 new world primates and 277 old world primates) for the first time, which is $0.62 \%$. A further 5 new world primates and 372 old world primates were re-used, taking the total number of animal experiments conducted on primates op to 704 ( $0.11 \%$ of the total number of animal experiments).

Since 2003 it has been prohibited to perform animal experiments on great apes (behaviourstudies consisting solely of observing the animals in their normal surroundings and which do not include any discomfort, harm, distress, etc. is not considered to be an experiment. Therefore these studies are exempted from the prohibition). In 2004 the last 6 experiments were conducted on chimpanzees, hence in 2005 no experiments on great apes were performed nor will there be any in the foreseeable future.

Inspectorate and inspections
The Food and Consumer Product Safety Authority (VWA) is responsible for enforcement of the legislation concerning laboratory animal welfare. The VWA conducted a total of 554 inspections in 2005 of which approximately $40 \%$ was unannounced beforehand. These inspections clearly showed that the regulations with direct regard to the welfare of the animals were in general well abided by.

In several cases infringements were detected. Depending on the severity of the infringement appropriate action was taken. In six cases the licence-holder received a written warning including a deadline for solving the problem. These licence-holders were told to solve the indicated infringement before a certain date. In every case the problems were solved when the inspector re-visited the licence-holder after the notified deadline. These infringements consisted of:

- housing of animals;
- entering remarks in a so-called welfare diary (which has to be present at the animal room to be used for recording all relevant welfare remarks);
- handling of and caring for the animals by not yet licensed personnel;
- conducting experiments on animals not bred/delivered by a licensed breeder without an exoneration by the VWA
- Conducting an experiment not according to the project plan, which had received a positive advice of the ethical review committee.

In 2005 fewer experiments were conducted than in 2004. Nearly half of the drop in number of animal experiments was due to a lower number of chicken experiments. This still was the result of the aftermath of the Avian Influenza outbreak in 2003. Many projects were postponed in 2003 due to the restrictions on transport of animals and eggs, hence a low number of chickens appeared in the 2003 statistics. In 2004 making up leeway led to a steep increase in use of chickens. In 2005 the situation was back to normal, thus the number dropped to normal levels.

## Type of experiments

Most animal experiments were conducted for developing, producing, checking or verifying of sera, vaccines, drugs, medical or veterinary products (47.3\%). Fundamental research was responsible for $44.2 \%$ of the total number of animal experiments. Potentially harming effects of substances covered $5.1 \%$, diagnostic procedures $1.4 \%$ and education and training $2.0 \%$. (These percentages are all based on the national statistics, hence including re-use and organ harvesting.)

Licence holding establishments
A licence to perform animal experiments is obliged in order to perform any experiment. In 2005 a total of 80 licence-holding establishments were registered by VWA. Three new licences were issued and one licence was terminated on request of the licence-holder.

In order to be allowed to breed an/or deliver laboratory animals a licence is mandatory as well. In 200541 establishments were licensed to breed a/o deliver laboratory animals. Most of which also have a licence to perform animal experiments.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | $\begin{gathered} 1.7 \\ \text { Re-used animals } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 240048 | 228666 | 0 | 7733 | 3649 | 5695 |
| 1.b. | Rats (Rattus norvegicus) | 116608 | 111973 | 0 | 4423 | 212 | 3357 |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 7479 | 4319 | 0 | 3150 | 10 | 46 |
| 1.d. | Hamsters (Mesocricetus ) | 5322 | 4961 | 0 | 357 | 4 | 13 |
| 1.e. | Other Rodents (other Rodentia) | 3089 | 1798 | 0 | 1167 | 124 | 521 |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 8251 | 7556 | 0 | 665 | 30 | 663 |
| 1.g. | Cats (Felis catus) | 334 | 233 | 0 | 30 | 71 | 14 |
| 1.h. | Dogs (Canis familiaris) | 1049 | 528 | 0 | 98 | 423 | 194 |
| 1.i. | Ferrets (Mustela putorius furo) | 256 | 21 | 0 | 50 | 185 | 0 |
| 1.j. | Other Carnivores (other Carnivora) | 151 | 0 | 0 | 0 | 151 | 0 |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 1705 | 541 | 0 | 0 | 1164 | 858 |
| 1.1. | Pigs (Sus) | 9853 | 4113 | 540 | 65 | 5135 | 63 |
| 1.m. | Goats (Capra) | 328 | 114 | 0 | 0 | 214 | 65 |
| 1.n. | Sheep (Ovis) | 2667 | 184 | 0 | 10 | 2473 | 152 |
| 1.0. | Cattle (Bos) | 4410 | 2602 | 3 | 81 | 1724 | 429 |
| 1.p. | Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. | New World Monkeys (Ceboidea) | 50 | 32 | 0 | 18 | 0 | 5 |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 277 | 223 | 0 | 35 | 19 | 185 |
| 1.s. | Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. | Other Mammals (other Mammalia) | 13 | 0 | 0 | 0 | 13 | 0 |
| 1.u. | Quail (Coturnix coturnix) | 152 | 0 | 0 | 152 | 0 | 0 |
| 1.v. | Other birds (other Aves) | 111081 | 15137 | 26 | 0 | 95918 | 603 |
| 1.w. | Reptiles (Reptilia) | 7 | 2 | 0 | 0 | 5 | 0 |
| 1.x. | Amphibians (Amphibia) | 3231 | 2877 | 0 | 7 | 347 | 0 |
| 1.y. | Fish (Pisces) | 14838 | 6906 | 683 | 1250 | 5999 | 119 |
| 1.z. | TOTAL | 531199 | 392786 | 1252 | 19291 | 117870 | 12982 |

 of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 143937 | 47957 | 14519 | 16107 | 6114 | 8704 | 2710 | 0 | 240048 |
| 2.b. | Rats | 34904 | 20931 | 32029 | 2769 | 23100 | 0 | 2875 | 0 | 116608 |
| 2.c. | Guinea-Pigs | 609 | 1553 | 1223 | 3621 | 429 | 3 | 41 | 0 | 7479 |
| 2.d. | Hamsters | 811 | 94 | 5 | 4356 | 45 | 0 | 11 | 0 | 5322 |
| 2.e. | Other Rodents | 197 | 2781 | 0 | 0 | 0 | 0 | 111 | 0 | 3089 |
| 2.f. | Rabbits | 751 | 1211 | 88 | 2222 | 3920 | 15 | 44 | 0 | 8251 |
| 2.g. | Cats | 129 | 33 | 0 | 83 | 6 | 0 | 83 | 0 | 334 |
| 2.h. | Dogs | 166 | 157 | 0 | 287 | 401 | 0 | 38 | 0 | 1049 |
| 2.i. | Ferrets | 136 | 108 | 0 | 0 | 0 | 0 | 12 | 0 | 256 |
| 2.j. | Other Carnivores | 151 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 151 |
| 2.k. | Horses, donkeys and cross breds | 2 | 163 | 65 | 1473 | 0 | 0 | 2 | 0 | 1705 |
| 2.1. | Pigs | 5336 | 2482 | 82 | 1725 | 56 | 0 | 172 | 0 | 9853 |
| 2.m. | Goats | 221 | 43 | 0 | 0 | 0 | 0 | 64 | 0 | 328 |
| 2.n. | Sheep | 211 | 194 | 2179 | 74 | 0 | 0 | 9 | 0 | 2667 |
| 2.0. | Cattle | 2930 | 875 | 53 | 322 | 0 | 0 | 230 | 0 | 4410 |
| 2.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.q. | New World Monkeys | 13 | 23 | 0 | 0 | 14 | 0 | 0 | 0 | 50 |
| 2.r. | Old World Monkeys | 196 | 71 | 10 | 0 | 0 | 0 | 0 | 0 | 277 |
| 2.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.t. | Other Mammals | 0 | 13 | 0 | 0 | 0 | 0 | 0 | 0 | 13 |
| 2.u. | Quail | 0 | 0 | 0 | 0 | 152 | 0 | 0 | 0 | 152 |
| 2.v. | Other birds | 34618 | 28022 | 333 | 47775 | 24 | 3 | 306 | 0 | 111081 |
| 2.w. | Reptiles | 6 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 7 |
| 2.x. | Amphibians | 3151 | 0 | 0 | 0 | 0 | 0 | 80 | 0 | 3231 |
| 2.y. | Fish | 7919 | 739 | 280 | 0 | 5384 | 0 | 516 | 0 | 14838 |
| 2.z. | TOTAL | 236394 | 107450 | 50866 | 80814 | 39645 | 8725 | 7305 | 0 | 531199 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Products versus species

|  | $\begin{gathered} \hline 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ <br> substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminants in the general environment which do not appear in other columns | 3.10 <br> Other toxicological or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 2819 | 92 | 2382 | 0 | 0 | 322 | 0 | 247 | 252 | 6114 |
| 3.b. | Rats | 6140 | 5574 | 8389 | 0 | 0 | 1558 | 479 | 0 | 960 | 23100 |
| 3.c. | Guinea-Pigs | 276 | 0 | 131 | 0 | 0 | 19 | 0 | 0 | 3 | 429 |
| 3.d. | Hamsters | 45 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 45 |
| 3.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.f. | Rabbits | 2554 | 885 | 371 | 0 | 0 | 6 | 104 | 0 | 0 | 3920 |
| 3.g. | Cats | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6 |
| 3.h. | Dogs | 301 | 100 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 401 |
| 3.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.1. | Pigs | 0 | 0 | 0 | 0 | 0 | 56 | 0 | 0 | 0 | 56 |
| 3.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.q. | New World Monkeys | 14 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 14 |
| 3.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.u. | Quail | 0 | 152 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 152 |
| 3.v. | Other birds | 0 | 24 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 24 |
| 3.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 3.y. | Fish | 0 | 350 | 180 | 0 | 0 | 0 | 0 | 4854 | 0 | 5384 |
| 3.z. | TOTAL | 12155 | 7177 | 11453 | 0 | 0 | 1961 | 583 | 5101 | 1215 | 39645 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 Studies specific to animal diseases | $\begin{gathered} \hline 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 15137 | 13750 | 48651 | 77344 | 12479 | 167361 |
| 4.b. | Rats | 3922 | 8641 | 2910 | 29959 | 50 | 45482 |
| 4.c. | Guinea-Pigs | 0 | 24 | 0 | 1794 | 145 | 1963 |
| 4.d. | Hamsters | 0 | 19 | 125 | 588 | 76 | 808 |
| 4.e. | Other Rodents | 0 | 0 | 0 | 2781 | 0 | 2781 |
| 4.f. | Rabbits | 340 | 5 | 28 | 1181 | 212 | 1766 |
| 4.g. | Cats | 0 | 1 | 0 | 24 | 69 | 94 |
| 4.h. | Dogs | 68 | 0 | 0 | 52 | 178 | 298 |
| 4.i. | Ferrets | 0 | 0 | 0 | 152 | 71 | 223 |
| 4.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 165 | 165 |
| 4.1. | Pigs | 277 | 0 | 21 | 511 | 3673 | 4482 |
| 4.m. | Goats | 89 | 0 | 0 | 142 | 2 | 233 |
| 4.n. | Sheep | 13 | 0 | 0 | 162 | 230 | 405 |
| 4.0. | Cattle | 0 | 0 | 0 | 61 | 1265 | 1326 |
| 4.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.q. | New World Monkeys | 0 | 5 | 0 | 27 | 0 | 32 |
| 4.r. | Old World Monkeys | 0 | 0 | 0 | 201 | 0 | 201 |
| 4.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.t. | Other Mammals | 0 | 0 | 0 | 13 | 0 | 13 |
| 4.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.v. | Other birds | 0 | 0 | 0 | 482 | 33870 | 34352 |
| 4.w. | Reptiles | 0 | 0 | 0 | 0 | 1 | 1 |
| 4.x. | Amphibians | 0 | 0 | 7 | 0 | 0 | 7 |
| 4.y. | Fish | 0 | 0 | 0 | 271 | 933 | 1204 |
| 4.z. | TOTAL | 19846 | 22445 | 51742 | 115745 | 53419 | 263197 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 5.4 Member Country of Council of Europe (but not EC) legislation 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice | 0 | 11126 | 0 | 1768 | 14929 | 2803 | 30626 |
| 5.b. | Rats | 0 | 3650 | 0 | 72 | 30483 | 593 | 34798 |
| 5.c. | Guinea-Pigs | 0 | 1139 | 7 | 0 | 2234 | 1464 | 4844 |
| 5.d. | Hamsters | 0 | 0 | 0 | 0 | 4354 | 7 | 4361 |
| 5.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.f. | Rabbits | 0 | 34 | 0 | 0 | 1996 | 280 | 2310 |
| 5.g. | Cats | 0 | 13 | 0 | 0 | 52 | 18 | 83 |
| 5.h. | Dogs | 0 | 0 | 0 | 0 | 149 | 138 | 287 |
| 5.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 136 | 1402 | 1538 |
| 5.1. | Pigs | 0 | 127 | 0 | 9 | 1248 | 423 | 1807 |
| 5.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.n. | Sheep | 8 | 0 | 0 | 0 | 26 | 2219 | 2253 |
| 5.0. | Cattle | 7 | 0 | 26 | 10 | 161 | 171 | 375 |
| 5.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 10 | 10 |
| 5.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.v. | Other birds | 40 | 0 | 0 | 0 | 37024 | 11044 | 48108 |
| 5.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 5.y. | Fish | 0 | 0 | 0 | 0 | 0 | 280 | 280 |
| 5.z. | TOTAL | 55 | 16089 | 33 | 1859 | 92792 | 20852 | 131680 |
| Examples: 5.2 - France is testing due to a UK (or FR) specific requirement <br>  5.3 - UK is testing according to EC legislation <br>  5.4 - Spain is testing due to a Hungarian requirement <br>  5.5 - Sweden is testing due to a US specific requirement <br>  5.6 - Germany is testing due to a Czech requirement (also an EC <br>  requirement) |  |  |  | Example: a test required by French legislat ISO protocol must be coded as a entered into column 5.2 in the ta |  | imposing that the test tual test method, guide nd carried out in Belgi al (FR) legislative req bmitted by Belgium. | carried out and or protocol. ccording to an ment and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 National legislation specific to a single EC Member State 1) | 6.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 6.4 <br> Member Country of Council <br> of Europe (but not EC) <br> legislation <br> 2) | 6.5 Other legislation | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | 6.7 <br> No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice | 0 | 0 | 0 | 84 | 4125 | 1905 | 6114 |
| 6.b. | Rats | 86 | 0 | 0 | 272 | 21161 | 1581 | 23100 |
| 6.c. | Guinea-Pigs | 0 | 0 | 0 | 0 | 400 | 29 | 429 |
| 6.d. | Hamsters | 0 | 0 | 0 | 0 | 45 | 0 | 45 |
| 6.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.f. | Rabbits | 0 | 0 | 0 | 0 | 3914 | 6 | 3920 |
| 6.g. | Cats | 0 | 0 | 0 | 6 | 0 | 0 | 6 |
| 6.h. | Dogs | 0 | 0 | 0 | 0 | 401 | 0 | 401 |
| 6.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.1. | Pigs | 0 | 0 | 0 | 0 | 56 | 0 | 56 |
| 6.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 14 | 14 |
| 6.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.u. | Quail | 0 | 0 | 0 | 0 | 152 | 0 | 152 |
| 6.v. | Other birds | 0 | 0 | 0 | 0 | 0 | 24 | 24 |
| 6.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 6.y. | Fish | 321 | 0 | 0 | 0 | 3830 | 1233 | 5384 |
| 6.z. | TOTAL | 407 | 0 | 0 | 362 | 34084 | 4792 | 39645 |
| Examples: 6.2 - France is tes <br>  6.3 - UK is testing <br>  6.4 - Spain is test <br>  6.5 - Sweden is te <br>  6.6 - Germany i |  | a UK (or FR) specifi to EC legislation a Hungarian requiren o a US specific requir due to a Czech requ | quirement <br> ent <br> ment (also an EC | Example: a test required by French legislati ISO protocol must be coded as a entered into column 6.2 in the tab |  | imposing that the tes tual test method, guid d carried out in Belgi al (FR) legislative req bmitted by Belgium. | carried out and or protocol. ccording to an nent and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} \hline 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2 <br> Acute and sub-acute toxicity testing methods (including limit test) |  |  | 7.3 <br> Skin irritation | 7.4 Skin sensitisatio n | 7.5 Eye irritation | 7.6 Sub- chronic and chronic toxicity | $7.7$ <br> Carcinogenicity | $\overline{7.8}$ <br> Developmental toxicity | 7.9 Muta- genicit $y$ | 7.10 <br> Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 7.12 \\ & \text { Other } \end{aligned}$ | $\begin{aligned} & \hline 7.13 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 0 | 10 | 839 | 0 | 2077 | 0 | 134 | 236 | 0 | 2435 | 0 | 0 | 383 | 6114 |
| 7.b. | Rats | 0 | 1009 | 3818 | 611 | 0 | 0 | 3242 | 0 | 6661 | 471 | 4852 | 0 | 2436 | 23100 |
| 7.c. | Guinea-Pigs | 0 | 0 | 18 | 0 | 290 | 0 | 23 | 0 | 0 | 0 | 0 | 0 | 98 | 429 |
| 7.d. | Hamsters | 0 | 0 | 45 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 45 |
| 7.e. | Other Rodents | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.f. | Rabbits | 0 | 0 | 140 | 330 | 0 | 167 | 24 | 0 | 60 | 0 | 1719 | 0 | 1480 | 3920 |
| 7.g. | Cats | 0 | 0 | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6 |
| 7.h. | Dogs | 0 | 0 | 169 | 0 | 0 | 0 | 224 | 0 | 0 | 0 | 0 | 0 | 8 | 401 |
| 7.i. | Ferrets | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.1. | Pigs | 0 | 0 | 0 | 0 | 0 | 0 | 56 | 0 | 0 | 0 | 0 | 0 | 0 | 56 |
| 7.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.n. | Sheep | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.0. | Cattle | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 14 | 14 |
| 7.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.u. | Quail | 152 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 152 |
| 7.v. | Other birds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 24 | 24 |
| 7.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.x. | Amphibians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 7.y. | Fish | 1278 | 535 | 1713 | 0 | 0 | 0 | 790 | 0 | 804 | 0 | 0 | 264 | 0 | 5384 |
| 7.z. | TOTAL | 1430 | 1554 | 6748 | 941 | 2367 | 167 | 4493 | 236 | 7525 | 2906 | 6571 | 264 | 4443 | 39645 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products

| 8.1 <br> Products |  | 8.2 <br> Acute and sub-acute toxicity testing methods (including limit test) |  |  | $\begin{gathered} 8.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 8.4 Skin sensitisatio n | 8.5 Eye irritation | $\begin{gathered} \hline 8.6 \\ \text { Sub- } \\ \text { chronic } \\ \text { and } \\ \text { chronic } \\ \text { toxicity } \end{gathered}$ | 8.7 Carcino genicity | 8.8 <br> Developmental toxicity | $\begin{gathered} 8.9 \\ \text { Muta- } \\ \text { genicit } \\ y \end{gathered}$ | 8.10 Reproductive toxicity | 8.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & 8.12 \\ & \text { Other } \end{aligned}$ | $\begin{gathered} \hline 8.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 8.a. | Products/substances or devices for human medicine and dentistry and for veterinary medicine | 0 | 119 | 3200 | 228 | 419 | 6 | 1469 | 0 | 1275 | 1600 | 961 | 0 | 2878 | 12155 |
| 8.b. | Products/substances used or intended to be used mainly in agriculture | 152 | 74 | 6 | 57 | 66 | 12 | 446 | 0 | 5338 | 26 | 843 | 0 | 157 | 7177 |
| 8.c. | Products/substances used or intended to be used mainly in industry | 144 | 826 | 1761 | 653 | 1759 | 146 | 864 | 0 | 108 | 830 | 4179 | 0 | 183 | 11453 |
| 8.d. | Products/substances used or intended to be used mainly in the household | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8.e. | Products/substances used or intended to be used mainly as cosmetics or toiletries | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 8.f. | Products/substances used or intended to be used mainly as additives in food for human consumption | 0 | 0 | 68 | 3 | 79 | 3 | 1150 | 0 | 0 | 231 | 165 | 0 | 262 | 1961 |
| 8.g. | Products/substances used or intended to be used mainly as additives in food for animal consumption | 0 | 0 | 0 | 0 | 0 | 0 | 160 | 0 | 0 | 0 | 423 | 0 | 0 | 583 |
| 8.h. | Potential or actual contaminants in the general environment which do not appear in other columns | 1134 | 535 | 1713 | 0 | 0 | 0 | 404 | 28 | 804 | 219 | 0 | 264 | 0 | 5101 |
| 8.i. | Other toxicological or safety evaluations | 0 | 0 | 0 | 0 | 44 | 0 | 0 | 208 | 0 | 0 | 0 | 0 | 963 | 1215 |
| 8.j. | TOTAL | 1430 | 1554 | 6748 | 941 | 2367 | 167 | 4493 | 236 | 7525 | 2906 | 6571 | 264 | 4443 | 39645 |

## POLAND

## Statistical data submitted

The statistical data have been submitted by the Ministry of Science and Higher Education, Department of Scientific Research.

## Comments of the Polish authorities

In accordance with Directive 86/609/EEC regarding the protection of animals used for experimental and other scientific purposes, animal experiments in Poland are regulated by the Experiments on Animals Act (Act of 21 January 2005 on experiments on live animals, Dz.U. Nr 33, poz. 289). The Minister of Science and Higher Education is responsible for enforcing the act.

Every animal experiment to be performed has to be recommended by a recognized ethical review committee (Local Commission for Ethics in Animal Experiments (LKE)). At the moment 18 ethical review committees are recognized. They are supervised by National Commission for Ethics in Animal Experiments (KKE). Members of KKE and LKE are independent on public administration institutions and user establishments. Licenses to perform animal experiments in individual user establishments are issued by the Minister of Science and Higher Education after receiving positive National Commission's (KKE) opinion.

The data on the use of experimental animals in Poland in 2005 was collected for the first time, so the number of animals used cannot be compared with the figures for the preceding years. The data collected comply with the procedure agreed by the Member States and the Commission of the European Communities pursuant to Article 26 of Directive 86/609/EEC.

The total number of animals used in experiments in Poland in 2005 was 358,829 .
No animals were re-used.
Rodents accounted for $56,6 \%$ of all animals used - 202,983 animals.
No primates were used.
Cold-blooded animals (fish and amphibians) represented $15,7 \%$ of the animals used 56,292 animals.

For the species which should be obtained from registered breeding or supplying establishments within Poland, over $95 \%$ of animals listed were so sourced and less than $4,5 \%$ were sourced outside of EC or Council of Europe member countries.
$53,23 \%$ of the animals were used in biological studies.
$31,67 \%$ of the animals were used in the research, development, production and quality control of products and devices for human medicine, dentistry and veterinary medicine.
$6,18 \%$ of the animals were used in toxicological studies.
$8,93 \%$ of the animals were used for diagnosis of disease, education and other purposes.

No animals were used in the testing of cosmetics products. Using animals for the purpose of testing of cosmetics products is prohibited by Polish law.
Poland was also asked to provide some feed back to the following specific question:
Question: Could PL provide some background information which could explain the reasons for the significant use of other carnivores, other mammals, cattle, other rodents, quails, horses etc., pigs and other birds in comparison to other Member States?
Almost $80 \%$ of 'other rodents' used for experiments in Poland are conducted at one of the largest academic centres, which collaborates with international universities and research institutes. Many experiments within the framework of international research projects are performed in Poland. It is important to emphasize that these research studies chiefly concern environmental research and the procedures used in these studies have the lowest level of invasiveness. The other $20 \%$ are used for environmental research much of which is unique to Poland and Central Europe.

Other carnivores are used in environmental studies, the study of endangered species and the process of re-introducing indigenous species to Poland (eg, wolves, bears etc).

The number of horses, donkeys and crossbreeds used in experiments is higher than in other Member States due to the Polish tradition of horse-breeding. These include studying new breeding programmes, assessment of transport conditions and nutrition, for example.

Poland produces a large amount of pork, beef and milk, therefore scientific research on pigs and cows is undertaken to maintain and improve the quality of these products.

Use of other mammals is necessary because agriculture is a big industry in Poland and animal testing is needed to monitor the effects of modern farming on the environment. These experiments involve mainly boars, bats and European bison.

Quails are used for toxicology tests for national as well as European companies. Other birds are also used for toxicological tests of pharmacological substances (required by Polish law), and ecological field studies on bird populations and the influence of agriculture on the bird population.

## TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

## Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 <br> Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from <br> Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | $\begin{gathered} \hline 1.7 \\ \text { Re-used animals } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 126492 | 119158 | 2772 | 790 | 3772 |  |
| 1.b. | Rats (Rattus norvegicus) | 51558 | 50988 | 0 | 32 | 538 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 10763 | 10731 | 0 | 0 | 32 |  |
| 1.d. | Hamsters (Mesocricetus ) | 243 | 194 | 0 | 0 | 49 |  |
| 1.e. | Other Rodents (other Rodentia) | 10826 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 3101 | 2879 | 0 | 0 | 222 | 0 |
| 1.g. | Cats (Felis catus) | 121 | 67 | 0 | 0 | 54 | 0 |
| 1.h. | Dogs (Canis familiaris) | 618 | 419 | 0 | 0 | 199 | 0 |
| 1.i. | Ferrets (Mustela putorius furo) | 19 | 14 | 0 | 0 | 5 | 0 |
| 1.j. | Other Carnivores (other Carnivora) | 6970 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 681 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 7358 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 130 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 2023 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 13834 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. | New World Monkeys (Ceboidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.s. | Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. | Other Mammals (other Mammalia) | 5061 |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 1470 | 1470 | 0 | 0 | 0 |  |
| 1.v. | Other birds (other Aves) | 61148 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 121 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 13216 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 43076 |  |  |  |  |  |
| 1.z. | TOTAL | 358829 |  |  |  |  |  |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

## Purpose versus species

|  | $\begin{gathered} \hline 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 45285 | 28377 | 20196 | 3676 | 13370 | 14217 | 860 | 511 | 126492 |
| 2.b. | Rats | 33154 | 4018 | 5754 | 105 | 3709 | 3877 | 767 | 174 | 51558 |
| 2.c. | Guinea-Pigs | 579 | 0 | 7158 | 996 | 1557 | 444 | 21 | 8 | 10763 |
| 2.d. | Hamsters | 138 | 31 | 0 | 0 | 0 | 70 | 4 | 0 | 243 |
| 2.e. | Other Rodents | 10250 | 0 | 0 | 0 | 356 | 20 | 34 | 166 | 10826 |
| 2.f. | Rabbits | 754 | 68 | 1174 | 439 | 147 | 233 | 72 | 214 | 3101 |
| 2.g. | Cats | 24 | 0 | 45 | 50 | 0 | 0 | 2 | 0 | 121 |
| 2.h. | Dogs | 319 | 9 | 0 | 21 | 29 | 133 | 77 | 30 | 618 |
| 2.i. | Ferrets | 5 | 0 | 0 | 14 | 0 | 0 | 0 | 0 | 19 |
| 2.j. | Other Carnivores | 6970 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 6970 |
| 2.k. | Horses, donkeys and cross breds | 611 | 0 | 0 | 0 | 5 | 30 | 35 | 0 | 681 |
| 2.1. | Pigs | 6978 | 8 | 0 | 0 | 20 | 13 | 19 | 320 | 7358 |
| 2.m. | Goats | 60 | 6 | 0 | 0 | 0 | 36 | 27 | 1 | 130 |
| 2.n. | Sheep | 1796 | 61 | 0 | 0 | 72 | 0 | 63 | 31 | 2023 |
| 2.0. | Cattle | 12969 | 40 | 0 | 41 | 88 | 48 | 53 | 595 | 13834 |
| 2.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.r. | Old World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.t. | Other Mammals | 5058 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 5061 |
| 2.u. | Quail | 1033 | 0 | 0 | 0 | 372 | 0 | 65 | 0 | 1470 |
| 2.v. | Other birds | 17194 | 40126 | 472 | 758 | 120 | 302 | 529 | 1647 | 61148 |
| 2.w. | Reptiles | 80 | 0 | 0 | 0 | 0 | 0 | 41 | 0 | 121 |
| 2.x. | Amphibians | 12200 | 0 | 0 | 0 | 0 | 0 | 1016 | 0 | 13216 |
| 2.y. | Fish | 35536 | 0 | 0 | 0 | 2315 | 300 | 515 | 4410 | 43076 |
| 2.z. | TOTAL | 190993 | 72744 | 34799 | 6100 | 22160 | 19723 | 4203 | 8107 | 358829 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Products versus species

|  | $\begin{gathered} \hline 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ <br> substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminants in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 9186 | 24 |  |  |  | 40 |  | 100 | 4020 | 13370 |
| 3.b. | Rats | 1450 | 460 | 665 | 31 |  |  |  | 128 | 975 | 3709 |
| 3.c. | Guinea-Pigs | 1459 | 98 |  |  |  |  |  |  |  | 1557 |
| 3.d. | Hamsters |  |  |  |  |  |  |  |  |  | 0 |
| 3.e. | Other Rodents |  | 28 | 28 |  |  |  |  | 300 |  | 356 |
| 3.f. | Rabbits | 126 | 9 | 6 | 6 |  |  |  |  |  | 147 |
| 3.g. | Cats |  |  |  |  |  |  |  |  |  | 0 |
| 3.h. | Dogs |  |  |  |  |  |  |  | 29 |  | 29 |
| 3.i. | Ferrets |  |  |  |  |  |  |  |  |  | 0 |
| 3.j. | Other Carnivores |  |  |  |  |  |  |  |  |  | 0 |
| 3.k. | Horses, donkeys and cross breds |  | 5 |  |  |  |  |  |  |  | 5 |
| 3.1. | Pigs |  |  |  |  |  | 20 |  |  |  | 20 |
| 3.m. | Goats |  |  |  |  |  |  |  |  |  | 0 |
| 3.n. | Sheep |  |  |  |  |  |  |  | 72 |  | 72 |
| 3.0. | Cattle | 8 |  |  |  |  |  | 80 |  |  | 88 |
| 3.p. | Prosimians |  |  |  |  |  |  |  |  |  | 0 |
| 3.q. | New World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.s. | Apes |  |  |  |  |  |  |  |  |  | 0 |
| 3.t. | Other Mammals |  |  |  |  |  |  |  |  |  | 0 |
| 3.u. | Quail |  | 372 |  |  |  |  |  |  |  | 372 |
| 3.v. | Other birds |  |  |  |  |  |  | 120 |  |  | 120 |
| 3.w. | Reptiles |  |  |  |  |  |  |  |  |  | 0 |
| 3.x. | Amphibians |  |  |  |  |  |  |  |  |  | 0 |
| 3.y. | Fish | 200 | 2079 |  |  |  |  |  | 36 |  | 2315 |
| 3.z. | TOTAL | 12429 | 3075 | 699 | 37 | 0 | 60 | 200 | 665 | 4995 | 22160 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2Human cardiovascular <br> diseases | 4.3Human nervous and <br> mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 Studies specific to animal diseases | $\begin{gathered} \hline 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 2924 | 37604 | 7473 | 10829 | 3546 | 62376 |
| 4.b. | Rats | 3110 | 16646 | 550 | 6604 | 86 | 26996 |
| 4.c. | Guinea-Pigs |  | 4 |  |  | 444 | 448 |
| 4.d. | Hamsters |  |  |  | 70 |  | 70 |
| 4.e. | Other Rodents |  | 389 |  | 20 |  | 409 |
| 4.f. | Rabbits | 60 |  | 5 | 228 |  | 293 |
| 4.g. | Cats |  |  |  | 18 | 9 | 27 |
| 4.h. | Dogs |  |  | 9 |  | 148 | 157 |
| 4.i. | Ferrets |  |  |  |  |  | 0 |
| 4.j. | Other Carnivores |  |  |  |  | 35 | 35 |
| 4.k. | Horses, donkeys and cross breds | 8 |  |  |  | 36 | 44 |
| 4.1. | Pigs | 45 |  |  |  | 40 | 85 |
| 4.m. | Goats |  |  |  |  | 5 | 5 |
| 4.n. | Sheep | 4 |  |  | 21 | 42 | 67 |
| 4.0. | Cattle |  |  |  |  | 135 | 135 |
| 4.p. | Prosimians |  |  |  |  |  | 0 |
| 4.q. | New World Monkeys |  |  |  |  |  | 0 |
| 4.r. | Old World Monkeys |  |  |  |  |  | 0 |
| 4.s. | Apes |  |  |  |  |  | 0 |
| 4.t. | Other Mammals |  |  |  |  |  | 0 |
| 4.u. | Quail |  |  |  |  |  | 0 |
| 4.v. | Other birds |  |  |  | 152 | 490 | 642 |
| 4.w. | Reptiles |  |  |  |  |  | 0 |
| 4.x. | Amphibians |  |  |  |  |  | 0 |
| 4.y. | Fish |  |  |  |  | 500 | 500 |
| 4.z. | TOTAL | 6151 | 54643 | 8037 | 17942 | 5516 | 92289 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} \hline 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 EC legislation including European Pharmacopoeia (requirements) | 5.4 Member Country of Council of Europe (but not EC) legislation 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice | 7474 | 8615 |  | 705 | 2398 | 4680 | 23872 |
| 5.b. | Rats |  | 5412 |  | 129 | 318 |  | 5859 |
| 5.c. | Guinea-Pigs | 1408 | 5813 |  | 20 | 10 | 903 | 8154 |
| 5.d. | Hamsters |  |  |  |  |  |  | 0 |
| 5.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 5.f. | Rabbits | 596 | 300 |  | 16 | 501 | 200 | 1613 |
| 5.g. | Cats | 76 | 11 |  |  | 8 |  | 95 |
| 5.h. | Dogs | 21 |  |  |  |  |  | 21 |
| 5.i. | Ferrets | 14 |  |  |  |  |  | 14 |
| 5.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 5.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 5.1. | Pigs |  |  |  |  |  |  | 0 |
| 5.m. | Goats |  |  |  |  |  |  | 0 |
| 5.n. | Sheep |  |  |  |  |  |  | 0 |
| 5.0. | Cattle |  | 41 |  |  |  |  | 41 |
| 5.p. | Prosimians |  |  |  |  |  |  | 0 |
| 5.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 5.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
| 5.s. | Apes |  |  |  |  |  |  | 0 |
| 5.t. | Other Mammals |  |  |  |  |  |  | 0 |
| 5.u. | Quail |  |  |  |  |  |  | 0 |
| 5.v. | Other birds | 1230 |  |  |  |  |  | 1230 |
| 5.w. | Reptiles |  |  |  |  |  |  | 0 |
| 5.x. | Amphibians |  |  |  |  |  |  | 0 |
| 5.y. | Fish |  |  |  |  |  |  | 0 |
| 5.z. | TOTAL | 10819 | 20192 | 0 | 870 | 3235 | 5783 | 40899 |

Examples: $\quad 5.2$ - France is testing due to a UK (or FR) specific requirement 5.3 - UK is testing according to EC legislation 5.4 - Spain is testing due to a Hungarian requirement 5.5 - Sweden is testing due to a US specific requirement 5.6 - Germany is testing due to a Czech requirement (also an EC

## Note:

Example:
columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

## requirement)


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

## TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Regulatory requirements versus species



2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| 7.1 Species |  | 7.2Acute and sub-acute toxicity testing methods <br> (including limit test) |  |  | $\begin{gathered} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 7.4 Skin sensitisatio n | 7.5 Eye irritation | 7.6 Sub- chronic and chronic toxicity | 7.7 <br> Carcinog enicity | 7.8 <br> Developmental toxicity | 7.9 Muta- genicit $y$ | 7.10 Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{gathered} \hline 7.12 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 7.13 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 306 | 7370 | 152 |  |  |  | 364 |  |  |  |  |  | 5178 | 13370 |
| 7.b. | Rats | 165 |  | 385 |  |  |  | 1651 |  | 316 |  | 371 |  | 821 | 3709 |
| 7.c. | Guinea-Pigs |  | 420 | 756 | 60 | 313 |  |  |  |  |  |  |  | 8 | 1557 |
| 7.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.e. | Other Rodents | 56 |  |  |  |  |  | 300 |  |  |  |  |  |  | 356 |
| 7.f. | Rabbits |  |  |  | 72 |  | 36 |  |  |  |  |  |  | 39 | 147 |
| 7.g. | Cats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.h. | Dogs |  |  |  |  |  |  |  |  |  |  | 29 |  |  | 29 |
| 7.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.k. | Horses, donkeys and cross breds breds |  |  |  |  |  |  |  |  |  |  |  |  | 5 | 5 |
| 7.1. | Pigs |  |  |  |  |  |  |  |  |  |  |  |  | 20 | 20 |
| 7.m. | Goats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.n. | Sheep |  |  |  |  |  |  |  |  | 35 |  | 37 |  |  | 72 |
| 7.0. | Cattle |  |  |  |  |  |  |  |  |  |  |  |  | 88 | 88 |
| 7.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.s. | Apes |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.u. | Quail | 180 |  |  |  |  |  |  |  |  |  | 192 |  |  | 372 |
| 7.v. | Other birds |  |  |  |  |  |  |  |  |  |  |  |  | 120 | 120 |
| 7.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.y. | Fish | 2179 |  |  |  |  |  |  |  |  |  | 36 | 100 |  | 2315 |
| 7.z. | TOTAL | 2886 | 7790 | 1293 | 132 | 313 | 36 | 2315 | 0 | 351 | 0 | 665 | 100 | 6279 | 22160 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products


## PORTUGAL

## Statistical data submitted

The statistical data have been submitted by the "Ministério da Agricultura, Desenvolvimento Rural e das Pescas - Direcção Geral de Veterinária" (Ministry of Agriculture, Rural Development and Fisheries - General Direction of Veterinary Directorate for Animal Medicines and Products, Animal Welfare and Feed)

## Comments of Portuguese authorities

## 1. Total number of animals used by species

In 2005 , the total number of animals used for experimental and other scientific purposes in Portugal was 41621.
Compared to the data of 2002, where the total number of used animals was 44577, it means that with regard to 2005 it was a slight decrease on the use of animals of $6,6 \%$.
As in the previous report, Mice are the most commonly used species representing $68,04 \%$ of the total number of animals.

The second most used group of animals was Rats ( $16,32 \%$ ), the third is represented by the cold-blooded animals ( $11,53 \%$ ) and the fourth by the rabbits with $1,43 \%$. The group of Artio and Perissodactyla represent $1,11 \%$ of the total number of animals used and Carnivors represent only $0,09 \%$.

Rodents with rabbits represent $87,01 \%$ of the total number of animals used.
As in other previous reports, in Portugal, non-human primates were not used.

## Comparison with the data of the previous report (data of 2002)

The percentages of classes of animals used in 2002 (44577 animals) and in 2005 (41621 animals) are represented in the following table:

| Class of <br> animals (\%) | 2002 | 2005 |
| :--- | :---: | :---: |
| Mice | 62 | 68,04 |
| Rats | 27,6 | 16,32 |
| Guinea-pigs | 1,42 | 0,91 |
| Hamsters and <br> other rodents | 0,21 | 0,31 |
| Rabbits | 2,04 | 1,43 |
| Cold-blooded <br> animals | 5,38 | 11,53 |


| Quail and other <br> birds | 0,44 | 0,27 |
| :--- | :---: | :---: |
| Artio <br> Perissodactyla | 0,88 | 1,11 |
| Carnivors | 0,08 | 0,09 |

Looking at the data by groups of species, the two major increases that happened in 2005 are in the use of Cold-blooded animals and of Mice.

On the other hand, the biggest decrease was in the use of Rats.
The percentage of Rabbits decreased in 2005 but the percentage of Hamsters slightly increased.

Among the group of the Cold-blooded animals, the general increase was due to the increase on the use of Fish, as the numbers of Reptiles and Amphibians both decreased.

The use of Birds decreased too and this decrease was due to the reduction on the use of Quail but also on Other Birds too.

The use of Artio and Perisodactyla animals increased in 2005. The species that its use decreased among this group was only Goats but all the others increased.

## 2. Number of animals used by purposes of experiments

In 2005, the percentage of animals (total 41621) used by purposes of experiments was the following:

78,78\% of animals were used in Fundamental biology;
$6,78 \%$ in Research and development for human medicine, veterinary medicine, dentistry;
$5,09 \%$ in Production and quality control of products and devices in human medicine and dentistry ( $1,72 \%$ ) and veterinary medicine ( $3,37 \%$ );

3,02\% in Education and training;
2,68\% in Diagnosis of disease;
2,26\% in Toxicological and other safety evaluation;
$1,39 \%$ in Other purposes;
Referring to the use of species versus experimental purposes, the highest amount of use of Mice and of Rats is in Fundamental biology and in Research and development for human medicine, veterinary medicine, dentistry.

## Comparison with the data of the previous report (data of 2002).

The most significant increase in 2005 is the number of animals that were used for Fundamental biology, which increased from $64,11 \%$ in 2002, to $78,78 \%$ in 2005.

The other increase that occurred was in the percentage of animals used in Production and quality control of products and devices in human medicine and dentistry, which increased from $0,8 \%$ in 2002, to $1,72 \%$ in 2005.

The use of animals in the rest of the other categories decreased, for example:
The percentage of animals used for Toxicological and other safety evaluation decreased from 2,92\% to 2,26\% (from 1301 to 939 animals);
The percentage of animals used for Education and training decreased from 4,78\% to $3,02 \%$ (from 2132 to 1258 animals);
The percentage of animals used for Other purposes decreased from 2,41\% to 1,39\% (from 1075 to 577 animals)

## 1. Number of animals used for Toxicological and safety evaluation by type of products

In 2005, the use of animals in Toxicological and other safety evaluation represents only $2,26 \%$, which only refers to 939 animals, of a total of 41621 animals that were used for experimental purposes in Portugal.

Products or devices for human medicine and dentistry and for veterinary medicine represents $52,08 \%$ of the animal used for Toxicological and other safety evaluation; Potential or actual contaminants in the general environment which do not appear in other columns represents $21,30 \%$ and Other toxicological or safety evaluations represent 26,62\%.

## Comparison with the data of the previous report (data of 2002).

Compared to the data of 2002, in 2005 there was a decrease on the use of animals in Toxicological and other safety evaluation. The percentage of animals used for Toxicological and other safety evaluation decreased from 2,92\% to 2,26\% (from 1301 to 939 animals).
The data of 2002 refers to the same category of products that were tested in 2005.
Products or devices for human medicine and dentistry and for veterinary medicine represented, in 2002, 20,67\% of the animal used for Toxicological and other safety evaluation; Potential or actual contaminants in the general environment which do not appear in other columns represented $12,45 \%$ and Other toxicological or safety evaluations represent $66,88 \%$.

As in 2002, in 2005 the other groups of products/substances were not tested which means that, for example, there were no animals used for the purpose of evaluating the safety of Cosmetics or Additives in food for animal consumption.

In Portugal, in 2005, there happened a decrease in the number of animals used for Other toxicological or safety evaluation compared to 2002. In 2002, the number of animals used were $870(66,88 \%)$ and in 2005, $250(26,62 \%)$.

## 2. Number of animals used for the study of diseases

In 2005, the number of animals used for the Studies on humans and animals diseases was 19372, which represents $46,54 \%$ of the total number of animals ( 41621 animals) that were used.

The percentages of animals per type of diseases were:
3,28\% in Human cardiovascular diseases;
24,89\% in Human nervous and mental disorders;
2,28\% in Human cancer (excl. evaluation of carcino hazards);
68,15\% in Other human diseases;
1,40\% in Specific animal diseases.
The percentage of the number of animals used for studies of human diseases represents $98,6 \%$ (19101 animals) of the total number of animals used for all studies of diseases (19372 animals).
In 2005, the number of animals used to study animal diseases was only $271(1,40 \%)$ while in 2002, that number had been 1922, which means that in 2005, there was a decrease on the use of animals for the study of animal diseases.
In general terms, the proportion of animals used for the studies of diseases showed a slight change when compared to the 2002 data.
In 2005, Cold-blooded animals were not used to study any diseases

## 3. Number of animals used for Toxicological and other safety evaluations by the types of tests

As pointed out earlier, in 2005, the use of animals in Toxicological and other safety evaluation represents only $2,26 \%$, which only refers to 939 animals, of a total of 41621 animals that were used for experimental purposes in Portugal.

## Comparison with the data of the previous report (data of 2002).

The percentages of animals used in toxicity tests for Toxicological and other safety evaluation in 2002 ( 1301 animals) and in 2005 (939 animals) are represented in the following table:

| Type of tests (\%) | 2002 | 2005 |
| :--- | :---: | :---: |
| Acute and sub-acute <br> toxicity testing methods <br> (including limit test) | 14,37 | 37,6 |
| Irritation/sensitization <br> tests | 6,53 | 27,8 |
| Sub-chronic and chronic <br> toxicity | 0 | 0 |
| Mutagenicity and <br> carcinogenicity | 8,84 | 32 |
| Reproductive and <br> developmental toxicity | 49,19 | 0 |


| Toxicity of aquatic <br> vertebrates not included <br> in other columns | 0 | 0 |
| :--- | :---: | :---: |
| Other | 21,1 | 2,7 |

In 2005, the biggest percentage of use of animals is due to acute and sub-acute toxicity, which represents $37,6 \%$ and means that there was an increase of this type of tests related to the previous report (data 2002).

The use of animals used for Reproductive and developmental toxicity tests decreased from $49,19 \%$ in 2002 , to $0 \%$ in 2005.

Contrary to what happened for the 25 Member States, the use of animals in 2005 for "Other tests" decreased from $21,1 \%$ in 2002, to $2,7 \%$ in 2005.

## 4. Type of toxicity tests carried out for Toxicological and other safety evaluations of products

As pointed out earlier, in 2005, the use of animals in Toxicological and other safety evaluation represents only $2,26 \%$, which only refers to 939 animals, of a total of 41621 animals that were used for experimental purposes in Portugal.

## Comparison with the data of the previous report (data of 2002)

The numbers of animals used for Toxicological and other safety evaluation per types of products in 2002 (1301 animals) and in 2005 (939 animals) are represented in the following tables:

| Types of products (\%) | 2002 | 2005 |
| :--- | :---: | :---: |
| Products/substances or <br> devices for human <br> medicine and dentistry <br> and for veterinary <br> medicine | 269 | 689 |
| Potential or actual <br> contaminants in the <br> general environment <br> which do not appear in <br> other columns | 162 | 0 |
| Other toxicological or <br> safety evaluations | 870 | 250 |

In 2005, the number of animals used to test Products/substances or devices for human medicine and dentistry and for veterinary medicine were the following:

300 animals in Carcinogenicity and Mutagenicity (in 2002, they were 100 animals);

261 animals in Irritation/sensitisation tests (in 2002, they were 85 animals);
103 animals in Acute and sub-acute toxicity testing methods (including limit test) (in 2002, they were 40 animals).
25 animals in Other tests (in 2002, they were 44 animals).
In 2005, the number of animals used in the category Other toxicological or safety evaluations were 250 animals in Acute and sub-acute toxicity testing methods (including limit test) (in 2002, they were 230 animals in Acute and sub-acute toxicity testing methods (including limit test) and 640 animals in Reproductive and developmental toxicity tests).

## TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 Animals coming from elsewhere in the EC | $1.5$ <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | $\begin{gathered} 1.7 \\ \text { Re-used animals } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 28318 | 19975 | 5838 | 49 | 2456 | 50 |
| 1.b. | Rats (Rattus norvegicus) | 6793 | 2362 | 4236 |  | 195 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 379 | 102 |  |  | 277 |  |
| 1.d. | Hamsters (Mesocricetus ) | 129 | 18 | 111 |  |  |  |
| 1.e. | Other Rodents (other Rodentia) |  |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 594 | 349 |  |  | 245 | 20 |
| 1.g. | Cats (Felis catus) |  |  |  |  |  |  |
| 1.h. | Dogs (Canis familiaris) | 36 |  |  |  | 36 | 10 |
| 1.i. | Ferrets (Mustela putorius furo) |  |  |  |  |  |  |
| 1.j. | Other Carnivores (other Carnivora) |  |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 8 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 113 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 4 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 290 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 45 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) |  |  |  |  |  |  |
| 1.q. | New World Monkeys (Ceboidea) |  |  |  |  |  |  |
| 1.r. | Old World Monkeys (Cercopithecoidea) |  |  |  |  |  |  |
| 1.s. | Apes (Hominoidea) |  |  |  |  |  |  |
| 1.t. | Other Mammals (other Mammalia) | 1 |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) |  |  |  |  |  |  |
| 1.v. | Other birds (other Aves) | 112 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) |  |  |  |  |  | 12 |
| 1.x. | Amphibians (Amphibia) | 51 |  |  |  | 1 |  |
| 1.y. | Fish (Pisces) | 4748 |  |  |  |  |  |
| 1.z. | TOTAL | 41621 |  |  |  |  |  |

 of those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES
Purpose versus species

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry |  | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7Diagnosis of <br> disease | 2.8Education and <br> training | $\begin{gathered} 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 23396 | 1075 | 700 | 977 | 440 | 994 | 471 | 265 | 28318 |
| 2.b. | Rats | 4249 | 1612 |  |  | 200 | 113 | 561 | 58 | 6793 |
| 2.c. | Guinea-Pigs | 65 |  |  | 110 | 2 | 8 | 25 | 169 | 379 |
| 2.d. | Hamsters |  | 115 |  |  |  |  |  | 14 | 129 |
| 2.e. | Other Rodents |  |  |  |  |  |  |  |  |  |
| 2.f. | Rabbits | 3 | 19 | 15 | 245 | 261 | 1 | 25 | 25 | 594 |
| 2.g. | Cats |  |  |  |  |  |  |  |  |  |
| 2.h. | Dogs |  |  |  |  | 36 |  |  |  | 36 |
| 2.i. | Ferrets |  |  |  |  |  |  |  |  |  |
| 2.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |
| 2.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 8 |  | 8 |
| 2.1. | Pigs | 33 |  |  |  |  |  | 78 | 2 | 113 |
| 2.m. | Goats |  |  |  |  |  |  | 4 |  | 4 |
| 2.n. | Sheep | 272 |  |  | 4 |  |  | 8 | 6 | 290 |
| 2.0. | Cattle | 37 |  |  |  |  |  | 8 |  | 45 |
| 2.p. | Prosimians |  |  |  |  |  |  |  |  |  |
| 2.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |
| 2.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |
| 2.s. | Apes |  |  |  |  |  |  |  |  |  |
| 2.t. | Other Mammals |  | 1 |  |  |  |  |  |  | 1 |
| 2.u. | Quail |  |  |  |  |  |  |  |  |  |
| 2.v. | Other birds | 6 |  |  | 69 |  |  |  | 37 | 112 |
| 2.w. | Reptiles |  |  |  |  |  |  |  |  |  |
| 2.x. | Amphibians |  |  |  |  |  |  | 50 | 1 | 51 |
| 2.y. | Fish | 4728 |  |  |  |  |  | 20 |  | 4748 |
| 2.z. | TOTAL | 32789 | 2822 | 715 | 1405 | 939 | 1116 | 1258 | 577 | 41621 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Products versus species

|  | $\begin{gathered} 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ <br> substances <br> used or intended to be used mainly in industry | 3.5 <br> Products/ <br> substances <br> used or <br> intended to <br> be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminants in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 190 |  |  |  |  |  |  |  | 250 | 440 |
| 3.b. | Rats |  |  |  |  |  |  |  | 200 |  |  |
| 3.c. | Guinea-Pigs | 2 |  |  |  |  |  |  |  |  | 2 |
| 3.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |
| 3.e. | Other Rodents |  |  |  |  |  |  |  |  |  |  |
| 3.f. | Rabbits | 261 |  |  |  |  |  |  |  |  | 261 |
| 3.g. | Cats |  |  |  |  |  |  |  |  |  |  |
| 3.h. | Dogs | 36 |  |  |  |  |  |  |  |  | 36 |
| 3.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |
| 3.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |
| 3.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  |  |
| 3.1. | Pigs |  |  |  |  |  |  |  |  |  |  |
| 3.m. | Goats |  |  |  |  |  |  |  |  |  |  |
| 3.n. | Sheep |  |  |  |  |  |  |  |  |  |  |
| 3.0. | Cattle |  |  |  |  |  |  |  |  |  |  |
| 3.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |
| 3.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |  |
| 3.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |  |
| 3.s. | Apes |  |  |  |  |  |  |  |  |  |  |
| 3.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |
| 3.u. | Quail |  |  |  |  |  |  |  |  |  |  |
| 3.v. | Other birds |  |  |  |  |  |  |  |  |  |  |
| 3.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |
| 3.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |
| 3.y. | Fish |  |  |  |  |  |  |  |  |  |  |
| 3.z. | TOTAL | 489 |  |  |  |  |  |  | 200 | 250 | 939 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | $\begin{gathered} 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 Studies specific to animal diseases | $\begin{gathered} \hline 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 66 | 2126 | 436 | 12509 | 247 | 15384 |
| 4.b. | Rats | 459 | 2696 | 3 | 658 |  | 3816 |
| 4.c. | Guinea-Pigs |  |  |  | 2 |  | 2 |
| 4.d. | Hamsters | 111 |  |  | 14 |  | 125 |
| 4.e. | Other Rodents |  |  |  |  |  |  |
| 4.f. | Rabbits |  |  |  |  |  |  |
| 4.g. | Cats |  |  |  |  |  |  |
| 4.h. | Dogs |  |  |  |  |  |  |
| 4.i. | Ferrets |  |  |  |  |  |  |
| 4.j. | Other Carnivores |  |  |  |  |  |  |
| 4.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |
| 4.1. | Pigs |  |  | 2 |  | 2 | 4 |
| 4.m. | Goats |  |  |  |  |  |  |
| 4.n. | Sheep |  |  |  |  | 4 | 4 |
| 4.0. | Cattle |  |  |  |  |  |  |
| 4.p. | Prosimians |  |  |  |  |  |  |
| 4.q. | New World Monkeys |  |  |  |  |  |  |
| 4.r. | Old World Monkeys |  |  |  |  |  |  |
| 4.s. | Apes |  |  |  |  |  |  |
| 4.t. | Other Mammals |  |  |  |  |  |  |
| 4.u. | Quail |  |  |  |  |  |  |
| 4.v. | Other birds |  |  |  | 19 | 18 | 37 |
| 4.w. | Reptiles |  |  |  |  |  |  |
| 4.x. | Amphibians |  |  |  |  |  |  |
| 4.y. | Fish |  |  |  |  |  |  |
| 4.z. | TOTAL | 636 | 4822 | 441 | 13202 | 271 | 19372 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 EC legislation including European Pharmacopoeia (requirements) | 5.4 <br> Member Country of Council of Europe (but not EC) legislation <br> 2) | 5.5 Other legislation | $5.6$ <br> Any combination of 5.2/5.3/5.4/5.5 | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice | 977 |  |  |  |  | 700 | 1677 |
| 5.b. | Rats |  |  |  |  |  |  |  |
| 5.c. | Guinea-Pigs | 110 |  |  |  |  |  | 110 |
| 5.d. | Hamsters |  |  |  |  |  |  |  |
| 5.e. | Other Rodents |  |  |  |  |  |  |  |
| 5.f. | Rabbits | 220 | 40 |  |  |  |  | 260 |
| 5.g. | Cats |  |  |  |  |  |  |  |
| 5.h. | Dogs |  |  |  |  |  |  |  |
| 5.i. | Ferrets |  |  |  |  |  |  |  |
| 5.j. | Other Carnivores |  |  |  |  |  |  |  |
| 5.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |
| 5.1. | Pigs |  |  |  |  |  |  |  |
| 5.m. | Goats |  |  |  |  |  |  |  |
| 5.n. | Sheep | 4 |  |  |  |  |  | 4 |
| 5.0. | Cattle |  |  |  |  |  |  |  |
| 5.p. | Prosimians |  |  |  |  |  |  |  |
| 5.q. | New World Monkeys |  |  |  |  |  |  |  |
| 5.r. | Old World Monkeys |  |  |  |  |  |  |  |
| 5.s. | Apes |  |  |  |  |  |  |  |
| 5.t. | Other Mammals |  |  |  |  |  |  |  |
| 5.u. | Quail |  |  |  |  |  |  |  |
| 5.v. | Other birds | 69 |  |  |  |  |  | 69 |
| 5.w. | Reptiles |  |  |  |  |  |  |  |
| 5.x. | Amphibians |  |  |  |  |  |  |  |
| 5.y. | Fish |  |  |  |  |  |  |  |
| 5.z. | TOTAL | 1380 | 40 |  |  |  | 700 | 2120 |

5.2 - France is testing due to a UK (or FR) specific requirement
5.3 - UK is testing according to EC legislation
5.4 - Spain is testing due to a Hungarian requirement
5.5 - Sweden is testing due to a US specific requirement
5.6 - Germany is testing due to a Czech requirement (also an EC

Note: $\quad$ columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium.

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Regulatory requirements versus species


TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2Acute and sub-acute toxicity testing methods(including limit test) |  |  | $\begin{gathered} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 7.4Skinsensitisation | 7.5Eyeirritation | 7.6Sub-chronic andchronictoxicity | 7.7 <br> Carcinogenicity | $\overline{7.8}$ <br> Developmental toxicity | 7.9Muta-genicit$y$ | $7.10$ <br> Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 7.12 \\ & \text { Other } \end{aligned}$ | $\begin{aligned} & \hline 7.13 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | $\begin{aligned} & \hline 7.2 .1 \\ & \text { LD50, } \\ & \text { LC50 } \end{aligned}$ | 7.2.2 <br> Other lethal methods | 7.2.3 <br> Non lethal clinical signs methods |  |  |  |  |  |  |  |  |  |  |  |
| 7.a. | Mice | 100 | 215 |  |  |  |  |  |  |  | 100 |  |  | 25 | 440 |
| 7.b. | Rats |  |  |  |  |  |  |  | 200 |  |  |  |  |  | 200 |
| 7.c. | Guinea-Pigs |  | 2 |  |  |  |  |  |  |  |  |  |  |  | 2 |
| 7.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.e. | Other Rodents |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.f. | Rabbits |  |  |  |  |  | 261 |  |  |  |  |  |  |  | 261 |
| 7.g. | Cats |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.h. | Dogs |  |  | 36 |  |  |  |  |  |  |  |  |  |  | 36 |
| 7.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.1. | Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.m. | Goats |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.n. | Sheep |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.0. | Cattle |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.s. | Apes |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.u. | Quail |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.v. | Other birds |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.y. | Fish |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.z. | TOTAL | 100 | 217 | 36 |  |  | 261 |  | 200 |  | 100 |  |  | 25 | 939 |

TABLE 8：NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products

| $8.1$ <br> Products | $\begin{gathered} 8.2 \\ \begin{array}{c} \text { Acute and sub-acute toxicity testing } \\ \text { methods (including limit test) } \end{array} \end{gathered}$ |  |  | $\begin{gathered} \hline 8.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 8.4Skinsensitisation | $\begin{gathered} 8.5 \\ \text { Eye } \\ \text { irritation } \end{gathered}$ | 8.6 Sub－ <br> chronic and chronic toxicity | 8.7Carcino genicity | 8.8 <br> Develop－ mental toxicity | $\begin{gathered} 8.9 \\ \text { Muta- } \\ \text { genicit } \\ y \end{gathered}$ | 8.10 <br> Repro－ ductive toxicity | 8.11 <br> Toxicity to aquatic vertebra－ tes not included in other columns | $\begin{aligned} & \hline 8.12 \\ & \text { Other } \end{aligned}$ | $\begin{gathered} 8.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | $\begin{aligned} & \hline 8.2 .1 . \\ & \text { LD50, } \\ & \text { LC50 } \end{aligned}$ | 8．2．2 <br> Other lethal methods | 8．2．3 <br> Non lethal clinical signs methods |  |  |  |  |  |  |  |  |  |  |  |
| 8．a．Products／substances or devices for human medicine and dentistry and for veterinary medicine |  | 103 |  |  |  | 261 |  | 200 |  | 100 |  |  | 25 | 689 |
| 8．b． $\begin{aligned} & \text { Products／substances used or intended to } \\ & \text { be used mainly in agriculture }\end{aligned}$ |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8．c． $\begin{array}{l}\text { Products／substances used or intended to } \\ \text { be used mainly in industry }\end{array}$ <br> $8 . ⿱ 亠 䒑$  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8．d．Products／substances used or intended to be used mainly in the household |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8．e．Products／substances used or intended to be used mainly as cosmetics or toiletries |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8．f．Products／substances used or intended to be used mainly as additives in food for human consumption |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8．g．Products／substances used or intended to be used mainly as additives in food for animal consumption |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8．h．Potential or actual contaminants in the general environment which do not appear in other columns |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 8．i． $\begin{aligned} & \text { Other toxicological or safety } \\ & \text { evaluations }\end{aligned}$ | 100 | 150 |  |  |  |  |  |  |  |  |  |  |  | 250 |
| 8．j．TOTAL | 100 | 253 |  |  |  | 261 |  | 200 |  | 100 |  |  | 25 | 939 |

## FINLAND

## Statistical data submitted

The statistical data have been submitted by the " Maa - ja metsätalousministeriö Elintarvikeja terveysosasto" (Ministry of Agriculture and Forestry, Veterinary and Food Department).

## Comments of Finnish authorities

Report from Finland 2005
In year 2005, 256826 experimental animals were used in Finland. Fish were used $20 \%$ more than in 2004. The total amount of animals of other species used in experiments remained essentially unchanged from the previous year.

Due to the increase in fish use there was a $6 \%$ increase in the total number of experimental animals in 2005 in comparison to 2004. In recent years fish use has varied greatly from more than 500000 in years 2001 and 2002 to 78000 in year 2004 causing a great yearly variation in total number of experimental animals used in Finland.

The number of mice used in 2005 was $19 \%$ higher than the yearly average in 2000-2004, but of rats $12 \%$ lower, respectively. Of all experimental animals used $60 \%$ were rodents, and 93 $\%$ of fish are excluded from the total, respectively. No cats were used in Finland in 2005, but the number of dogs used was increasing third year in row, the number being 103 in 2005 which is $60 \%$ higher than the average yearly use of previous 5 years. Cattle was in 2005 used also increasingly in comparison to previous 5 years. In other species no tendency was seen.

No cats, monkeys and reptiles were reported used as experimental animals in Finland in 2005.
Major part ( $87 \%$ ) of the animals were used for biological studies of a fundamental nature. Animal use in 2005 for human and veterinary medicine research and quality control was 9,3 $\%$, for toxicological and other safety evaluations $0,9 \%$, for diagnosis of disease $0,2 \%$, for education and training $1,8 \%$ and other uses $0,9 \%$ of the total number of experimental animals used, respectively. No major differences in comparison to the previous year were observed.

Preparations for a revision of the Finnish legislation concerning use of experimental animals proceeded to final drafts during year 2005 and was planned to be passed in 2006.

Ministry of Agriculture and Forestry funded Finnish research for studies to replace existing techniques using experimental animals with alternative methods with $27000 €$ in year 2005.

## TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

## Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | $\begin{gathered} \hline 1.7 \\ \text { Re-used animals } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 120636 | 87684 | 32362 | 247 | 343 |  |
| 1.b. | Rats (Rattus norvegicus) | 28358 | 10869 | 17365 |  | 124 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 563 |  | 563 |  |  |  |
| 1.d. | Hamsters (Mesocricetus ) | 126 | 6 | 120 |  |  |  |
| 1.e. | Other Rodents (other Rodentia) | 3187 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 1214 | 500 | 714 |  |  |  |
| 1.g. | Cats (Felis catus) | 0 | 0 |  |  |  |  |
| 1.h. | Dogs (Canis familiaris) | 103 | 8 | 95 |  |  |  |
| 1.i. | Ferrets (Mustela putorius furo) | 80 | 80 |  |  |  |  |
| 1.j. | Other Carnivores (other Carnivora) | 5 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 125 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 1471 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 73 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 445 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 455 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 | 0 |  |  |  |  |
| 1.q. | New World Monkeys (Ceboidea) | 0 | 0 |  |  |  |  |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 0 | 0 |  |  |  |  |
| 1.s. | Apes (Hominoidea) | 0 | 0 |  |  |  |  |
| 1.t. | Other Mammals (other Mammalia) | 972 | 0 |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 0 | 0 |  |  |  |  |
| 1.v. | Other birds (other Aves) | 5773 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 0 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 20 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 93220 |  |  |  |  |  |
| 1.z. | TOTAL | 256826 | 100617 | 51229 | 247 | 468 |  |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

## Purpose versus species

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 111502 | 7761 | 100 |  | 585 | 25 | 581 | 82 | 120636 |
| 2.b. | Rats | 13749 | 11885 | 100 |  | 1374 | 17 | 791 | 442 | 28358 |
| 2.c. | Guinea-Pigs |  | 352 | 24 |  | 79 |  | 24 | 84 | 563 |
| 2.d. | Hamsters | 126 |  |  |  |  |  |  |  | 126 |
| 2.e. | Other Rodents | 3187 |  |  |  |  |  |  |  | 3187 |
| 2.f. | Rabbits | 514 | 467 | 54 |  | 75 | 1 | 85 | 18 | 1214 |
| 2.g. | Cats |  |  |  |  |  |  |  |  | 0 |
| 2.h. | Dogs |  | 47 |  |  | 56 |  |  |  | 103 |
| 2.i. | Ferrets | 80 |  |  |  |  |  |  |  | 80 |
| 2.j. | Other Carnivores | 5 |  |  |  |  |  |  |  | 5 |
| 2.k. | Horses, donkeys and cross breds | 110 | 15 |  |  |  |  |  |  | 125 |
| 2.1. | Pigs | 445 | 141 | 203 |  |  |  | 82 | 600 | 1471 |
| 2.m. | Goats |  | 4 |  |  |  |  | 69 |  | 73 |
| 2.n. | Sheep | 22 | 43 | 380 |  |  |  |  |  | 445 |
| 2.0. | Cattle | 277 |  |  |  |  |  | 178 |  | 455 |
| 2.p. | Prosimians |  |  |  |  |  |  |  |  | 0 |
| 2.q. | New World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.r. | Old World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.s. | Apes |  |  |  |  |  |  |  |  | 0 |
| 2.t. | Other Mammals | 972 |  |  |  |  |  |  |  | 972 |
| 2.u. | Quail |  |  |  |  |  |  |  |  | 0 |
| 2.v. | Other birds | 2515 | 8 |  | 2209 |  |  | 41 | 1000 | 5773 |
| 2.w. | Reptiles |  |  |  |  |  |  |  |  | 0 |
| 2.x. | Amphibians |  |  |  |  |  |  | 20 |  | 20 |
| 2.y. | Fish | 90011 |  |  |  | 72 | 317 | 2820 |  | 93220 |
| 2.z. | TOTAL | 223515 | 20723 | 861 | 2209 | 2241 | 360 | 4691 | 2226 | 256826 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Products versus species

|  | $\begin{gathered} \hline 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ <br> substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminants in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 265 |  |  |  |  |  |  |  | 320 | 585 |
| 3.b. | Rats | 758 |  |  |  |  |  |  |  | 616 | 1374 |
| 3.c. | Guinea-Pigs | 79 |  |  |  |  |  |  |  |  | 79 |
| 3.d. | Hamsters |  |  |  |  |  |  |  |  |  | 0 |
| 3.e. | Other Rodents |  |  |  |  |  |  |  |  |  | 0 |
| 3.f. | Rabbits | 75 |  |  |  |  |  |  |  |  | 75 |
| 3.g. | Cats |  |  |  |  |  |  |  |  |  | 0 |
| 3.h. | Dogs | 56 |  |  |  |  |  |  |  |  | 56 |
| 3.i. | Ferrets |  |  |  |  |  |  |  |  |  | 0 |
| 3.j. | Other Carnivores |  |  |  |  |  |  |  |  |  | 0 |
| 3.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  | 0 |
| 3.1. | Pigs |  |  |  |  |  |  |  |  |  | 0 |
| 3.m. | Goats |  |  |  |  |  |  |  |  |  | 0 |
| 3.n. | Sheep |  |  |  |  |  |  |  |  |  | 0 |
| 3.0. | Cattle |  |  |  |  |  |  |  |  |  | 0 |
| 3.p. | Prosimians |  |  |  |  |  |  |  |  |  | 0 |
| 3.q. | New World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.s. | Apes |  |  |  |  |  |  |  |  |  | 0 |
| 3.t. | Other Mammals |  |  |  |  |  |  |  |  |  | 0 |
| 3.u. | Quail |  |  |  |  |  |  |  |  |  | 0 |
| 3.v. | Other birds |  |  |  |  |  |  |  |  |  | 0 |
| 3.w. | Reptiles |  |  |  |  |  |  |  |  |  | 0 |
| 3.x. | Amphibians |  |  |  |  |  |  |  |  |  | 0 |
| 3.y. | Fish |  |  |  |  |  |  |  | 72 |  | 72 |
| 3.z. | TOTAL | 1233 | 0 | 0 | 0 | 0 | 0 | 0 | 72 | 936 | 2241 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | $\begin{gathered} \hline 4.3 \\ \text { Human nervous and } \end{gathered}$ mental disorders | 4.4 <br> Human cancer (excluding evaluations of carcinogenic hazards or risks) | 4.5 Other human diseases | 4.6 <br> Studies specific to animal diseases | $\begin{gathered} \hline 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 3629 | 6400 | 8652 | 18885 |  | 37566 |
| 4.b. | Rats | 3408 | 9683 | 266 | 4118 |  | 17475 |
| 4.c. | Guinea-Pigs | 332 |  |  |  |  | 332 |
| 4.d. | Hamsters |  |  |  | 120 |  | 120 |
| 4.e. | Other Rodents |  |  |  |  |  | 0 |
| 4.f. | Rabbits | 195 | 15 |  | 362 |  | 572 |
| 4.g. | Cats |  |  |  |  |  | 0 |
| 4.h. | Dogs | 75 | 12 |  |  |  | 87 |
| 4.i. | Ferrets |  |  |  |  |  | 0 |
| 4.j. | Other Carnivores |  |  |  |  |  | 0 |
| 4.k. | Horses, donkeys and cross breds |  |  |  |  |  | 0 |
| 4.1. | Pigs | 218 |  |  |  |  | 218 |
| 4.m. | Goats |  |  |  |  |  | 0 |
| 4.n. | Sheep |  |  |  | 39 | 22 | 61 |
| 4.0. | Cattle |  |  |  |  | 6 | 6 |
| 4.p. | Prosimians |  |  |  |  |  | 0 |
| 4.q. | New World Monkeys |  |  |  |  |  | 0 |
| 4.r. | Old World Monkeys |  |  |  |  |  | 0 |
| 4.s. | Apes |  |  |  |  |  | 0 |
| 4.t. | Other Mammals |  |  |  |  | 6 | 6 |
| 4.u. | Quail |  |  |  |  |  | 0 |
| 4.v. | Other birds |  |  |  |  | 8 | 8 |
| 4.w. | Reptiles |  |  |  |  |  | 0 |
| 4.x. | Amphibians |  |  |  |  |  | 0 |
| 4.y. | Fish |  |  |  |  | 385 | 385 |
| 4.z. | TOTAL | 7857 | 16110 | 8918 | 23524 | 427 | 56836 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} \hline 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 EC legislation including European Pharmacopoeia (requirements) | 5.4 Member Country of Council of Europe (but not EC) legislation 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice |  | 80 | 20 |  |  |  | 100 |
| 5.b. | Rats |  |  |  |  |  | 100 | 100 |
| 5.c. | Guinea-Pigs |  |  |  |  |  | 24 | 24 |
| 5.d. | Hamsters |  |  |  |  |  |  | 0 |
| 5.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 5.f. | Rabbits |  | 4 |  |  |  | 50 | 54 |
| 5.g. | Cats |  |  |  |  |  |  | 0 |
| 5.h. | Dogs |  |  |  |  |  |  | 0 |
| 5.i. | Ferrets |  |  |  |  |  |  | 0 |
| 5.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 5.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 5.1. | Pigs |  |  |  |  | 171 | 32 | 203 |
| 5.m. | Goats |  |  |  |  |  |  | 0 |
| 5.n. | Sheep |  |  |  |  | 380 |  | 380 |
| 5.0. | Cattle |  |  |  |  |  |  | 0 |
| 5.p. | Prosimians |  |  |  |  |  |  | 0 |
| 5.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 5.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
| 5.s. | Apes |  |  |  |  |  |  | 0 |
| 5.t. | Other Mammals |  |  |  |  |  |  | 0 |
| 5.u. | Quail |  |  |  |  |  |  | 0 |
| 5.v. | Other birds |  |  |  |  |  | 2209 | 2209 |
| 5.w. | Reptiles |  |  |  |  |  |  | 0 |
| 5.x. | Amphibians |  |  |  |  |  |  | 0 |
| 5.y. | Fish |  |  |  |  |  |  | 0 |
| 5.z. | TOTAL | 0 | 84 | 20 | 0 | 551 | 2415 | 3070 |

Examples:
5.2 - France is testing due to a UK (or FR) specific requirement
5.3- UK is testing according to EC legislation
5.4 - Spain is testing due to a Hungarian requirement 5.5 - Sweden is testing due to a US specific requirement
5.6 - Germany is testing due to a Czech requirement (also an EC

Note: columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

## TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 National legislation specific to a single EC Member State 1) | 6.3 EC legislation including European Pharmacopoeia (requirements) | 6.4 <br> Member Country of Council <br> of Europe (but not EC) <br> legislation <br> 2) | $\begin{gathered} \hline 6.5 \\ \text { Other legislation } \end{gathered}$ | $\begin{gathered} \hline 6.6 \\ \text { Any combination of } \\ 6.2 / 6.3 / 6.4 / 6.5 \end{gathered}$ | $\begin{gathered} \hline 6.7 \\ \text { No regulatory } \\ \text { requirements } \end{gathered}$ | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice | 40 | 55 |  |  | 490 |  | 585 |
| 6.b. | Rats |  | 127 |  |  | 1151 | 96 | 1374 |
| 6.c. | Guinea-Pigs |  |  |  |  | 79 |  | 79 |
| 6.d. | Hamsters |  |  |  |  |  |  | 0 |
| 6.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 6.f. | Rabbits |  | 8 |  |  | 67 |  | 75 |
| 6.g. | Cats |  |  |  |  |  |  | 0 |
| 6.h. | Dogs |  | 56 |  |  |  |  | 56 |
| 6.i. | Ferrets |  |  |  |  |  |  | 0 |
| 6.j. | Other Carnivores |  |  |  |  |  |  | 0 |
|  | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 6.1. | Pigs |  |  |  |  |  |  | 0 |
| 6.m | Goats |  |  |  |  |  |  | 0 |
| 6.n. | Sheep |  |  |  |  |  |  | 0 |
| 6.0. | Cattle |  |  |  |  |  |  | 0 |
| 6.p. | Prosimians |  |  |  |  |  |  | 0 |
| 6.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 6.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
| 6.s. | Apes |  |  |  |  |  |  | 0 |
|  | Other Mammals |  |  |  |  |  |  | 0 |
| 6.u. | Quail |  |  |  |  |  |  | 0 |
| 6.v. | Other birds |  |  |  |  |  |  | 0 |
| 6.w | Reptiles |  |  |  |  |  |  | 0 |
| 6.x. | Amphibians |  |  |  |  |  |  | 0 |
| 6.y. | Fish |  |  |  |  |  | 72 | 72 |
| 6.z. | TOTAL | 40 | 246 | 0 | 0 | 1787 | 168 | 2241 |
| Examples: 6.2 - France is testing due to a UK (or FR) specific requirement <br>  6.3 - UK is testing according to EC legislation <br>  6.4 - Spain is testing due to a Hungarian requirement <br>  6.5 - Sweden is testing due to a US specific requirement <br>  6.6 - Germany is testing due to a Czech requirement (also an EC <br>  requirement) |  |  |  | Note: columns $6.2-$ <br>  not to the bod <br> Example: a test require <br>  ISO protocol <br>  entered into | which has issued y French legislat st be coded as a umn 6.2 in the tab | imposing that the tes tual test method, guid d carried out in Belgi (FR) legislative req bmitted by Belgium. | carried out and or protocol. ccording to an nent and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2Acute and sub-acute toxicity testing methods <br> (including limit test) |  |  | $\begin{gathered} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 7.4 Skin sensitisatio n | 7.5 Eye irritation | 7.6 Sub- chronic and chronic toxicity | 7.7 <br> Carcinogenicity | $7.8$ <br> Developmental toxicity | 7.9 Muta- genicit $y$ | 7.10 Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{gathered} \hline 7.12 \\ \text { Other } \end{gathered}$ | $\begin{gathered} \hline 7.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice |  |  | 375 |  |  |  | 40 |  |  |  |  |  | 170 | 585 |
| 7.b. | Rats |  |  | 520 |  |  |  | 17 |  |  |  | 100 |  | 737 | 1374 |
| 7.c. | Guinea-Pigs |  |  |  |  |  |  |  |  |  |  |  |  | 79 | 79 |
| 7.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.e. | Other Rodents |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.f. | Rabbits |  |  |  |  |  |  | 8 |  |  |  |  |  | 67 | 75 |
| 7.g. | Cats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.h. | Dogs |  |  |  |  |  |  | 56 |  |  |  |  |  |  | 56 |
| 7.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.k. | Horses, donkeys and cross breds breds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.1. | Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.m. | Goats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.n. | Sheep |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.0. | Cattle |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.s. | Apes |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.u. | Quail |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.v. | Other birds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.y. | Fish |  |  |  |  |  |  |  |  |  |  |  | 72 |  | 72 |
| 7.z. | TOTAL | 0 | 0 | 895 | 0 | 0 | 0 | 121 | 0 | 0 | 0 | 100 | 72 | 1053 | 2241 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products

| $8.1$ <br> Products | 8.2Acute and sub-acute toxicity testing <br> methods (including limit test) |  |  | $\begin{gathered} \hline 8.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 8.4Skinsensitisation | 8.5Eyeirritation | 8.6 Sub- <br> chronic and chronic toxicity | 8.7Carcino genicity | 8.8 <br> Developmental toxicity | 8.9Muta-genicity | 8.10 <br> Reproductive toxicity | 8.11Toxicityto aquaticvertebra-tes notincludedin othercolumns | $\begin{aligned} & \hline 8.12 \\ & \text { Other } \end{aligned}$ | $\begin{gathered} \hline 8.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | $\begin{gathered} \hline 8.2 .1 . \\ \text { LD50, } \\ \text { LC50 } \end{gathered}$ | 8.2 .2 <br> Other lethal <br> methods | 8.2.3 <br> Non lethal clinical signs methods |  |  |  |  |  |  |  |  |  |  |  |
| 8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine |  |  | 895 |  |  |  | 121 |  |  |  | 100 |  | 957 | 2073 |
| 8.b.Products/substances used or intended to <br> be used mainly in agriculture |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.c. $\begin{aligned} & \text { Products/substances used or intended to } \\ & \text { be used mainly in industry }\end{aligned}$ |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.d. $\begin{aligned} & \text { Products/substances used or intended to } \\ & \text { be used mainly in the household }\end{aligned}$ |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.f. Products/substances used or intended to be used mainly as additives in food for human consumption |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns |  |  |  |  |  |  |  |  |  |  |  | 72 |  | 72 |
| 8.i. $\begin{aligned} & \text { Other toxicological or safety } \\ & \text { evaluations }\end{aligned}$ |  |  |  |  |  |  |  |  |  |  |  |  | 96 | 96 |
| 8.j. TOTAL | 0 | 0 | 895 | 0 | 0 | 0 | 121 | 0 | 0 | 0 | 100 | 72 | 1053 | 2241 |

## SLOVENIA

## Statistical data submitted

The statistical data have been submitted by the "Veterinary Administration of the Republic of Slovenia"

## Comments of Slovenian authorities

The Slovenian national legislation on the protection of experimental animals has been harmonised with the relevant EU legislation. Experimental animals have been regulated under the Protection of Animals Act (UPB-1, UL RS ${ }^{7}$ 20/04), under the Rules on conditions for experiments on animals (UL RS 88/06), and under the Rules on the Ethical Commission for experiments on animals (UL RS 84/00).

On the basis of annual reports submitted by organisations conducting experiments on animals, the Veterinary Administration of the Republic of Slovenia (VARS) has been keeping statistical records including the data on quantities and species of animals used in experiments and types of experiments as laid down in Article 24 (2) of the Protection of Animals Act. Each user organisation employs an animal welfare expert, who is responsible for compiling on a specifically prescribed form a collective annual report on experiments conducted during the year and for submitting the report by the end of February to VARS. The form envisaged for annual reporting includes eight tables and as Annex 5 constitutes an integral part of the Rules on conditions for experiments on animals.

In the Republic of Slovenia, data on the use of animals in experiments have been collected since 1992. In the period 1992 - 1996, the collective number of animals used in experiments ranged on average up to 33,000 animals, in the period $1997-$ 1999 up to 21,000 animals, in the period $2000-2001$ up to 16,000 animals, and in the period $2002-2004$ on average up to 13,500 animals. In the light of the above it may be stated with certainty that the use of animals in experiments in the Republic of Slovenia has been showing a downward trend.

In 2005, a collective number of animals used for experimental and other scientific purposes totalled 11,991 animals. As compared to 2004, where 13,538 animals were used in experiments, the number of animals used in experiments in 2005 decreased by 1,547 animals ( $11.4 \%$ ). This collective number of animals mostly included laboratory rodents (mice, rats) and rabbits.

In 2005, 11,344 laboratory rodents were used, amounting to $94.6 \%$ of all experimental animals used, whilst more laboratory rodents were used in 2004, i.e. 12,145 animals or $89.7 \%$ of all experimental animals used. In 2005, 533 rabbits were used in experiments, amounting to $8.5 \%$ less rabbits as compared to 2004. In 2005, a collective number of 114 other animals were used, including in particular sheep, birds, pigs and a horse.

[^3]It is evident from Table 1 showing the number and species of animals used in relation to their place of origin that nearly all laboratory experimental animals in 2005 came from breeding organisations established within the Republic of Slovenia. Mostly used were laboratory rodents ( $94.6 \%$ ). From the collective number of experimental animals, the animals reused in experiments included the rabbits and dogs.

As regards animals used in experiments for selected purposes as shown in Table 2, in 2005, most animals were used in pharmaceutical industry in the Republic of Slovenia. For the purposes of research and development of products and devices for human medicine, and for dentistry and veterinary medicine, for the production and quality control of products and devices for human and veterinary medicine, and for toxicological and other safety evaluations, a total of 9,420 animals, or $78.5 \%$ of all animals used ( $94 \%$ laboratory rodents, $5.4 \%$ rabbits and $0.4 \%$ sheep), were used in such experiments in 2005.

Table 3 shows that a total of 1,054 animals were used in the toxicological and other safety evaluations. A total of 1,009 animals ( 975 laboratory rodents and 34 sheep) were used for testing products/substances or devices for human medicine, dentistry and veterinary medicine, and 45 rabbits for other toxicological or safety evaluations.

Table 7 details the use of animals in the toxicological and other safety evaluations. In 2005, 965 laboratory rodents were used in the acute and sub-acute toxicity testing methods, or in LD 50 and LC 50 determination, and 10 laboratory rats, 45 rabbits and 34 sheep in other toxicological and safety evaluations.

Table 8 shows that 965 animals were used in the toxicological and other safety evaluations for products/substances or devices for human medicine, dentistry and veterinary medicine, and 34 animals for other purposes of toxicological or safety evaluations, whilst 55 animals were used in tests of reproduction toxicity of products/substances intended for use in agriculture.

Quality control of products and devices for human medicine, dentistry and veterinary medicine, and toxicological and other safety evaluations of substances are conducted in accordance with the applicable legislation, the requirements of relevant Pharmacopoeias, and in accordance with the international regulations.

Table 5 shows that in accordance with EU legislation, including the requirements of the European Pharmacopoeia, 5,916 animals in total were used in the production and quality control of products and devices for human medicine and dentistry and for veterinary medicine, which amounts to $49.3 \%$ of all experimental animals used in 2005. Laboratory rodents and rabbits were used for these purposes.

The institutes and laboratories of the faculties of human medicine, veterinary medicine, biology and zootechnics use animals in the baseline biological research studies and/or in the research and development studies, and a total of 1,888 animals were used for these purposes in 2005, which amounts to $15.7 \%$ of all animals used, including in particular laboratory rodents ( $98.9 \%$ ), some dogs, sheep and birds.

In 2005, animals were used to a lesser extent for diagnosing diseases (3.1 \%), educational and training purposes ( $2.3 \%$ ), and other purposes ( $0.1 \%$ ).

Table 4 shows the number and species of animals used in experiments for studies of diseases in humans and in animals. A total of 1,786 animals were used for these purposes, all for studies of diseases in humans. A total of 735 animals were used for studies of nervous and mental disorders in humans, 422 animals for studies of cardiovascular diseases, and 629 animals for studies of other diseases. Laboratory rodents were used predominantly, and some rabbits and sheep.

An important role in decreasing the number of animals used in experiments plays in particular the legislation, and the substitution of animals by alternative methods where so required by law, the requirement for specific authorisations of experiments, appropriate staff training, successful cooperation between the institutes and researchers at the national and international levels, as well as the active involvement of animal protection and welfare societies. A further important contribution to decreasing the number of animals used in experiments is the responsibility on the part of researchers and their improved attitude towards experimental animals as the plans and protocols of experiments are more precise and detailed, methods more carefully selected and experiments more precisely conducted. Further important factors in decreasing the number of animals used in experiments particularly in the pharmaceutical industry include the interstate/international recognition of results obtained in experiments on animals, the improved biometric methods, improved initial research phases of new substances and the use of cell cultures, tissues or smaller groups of animals.

Dr. Dragica Ornik,
Inspector - Counsellor
Dr. Vida Čadonič Špelič,
Chief Veterinary Officer

## TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

## Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 <br> Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 8556 | 8556 |  |  |  |  |
| 1.b. | Rats (Rattus norvegicus) | 2732 | 2727 | 5 |  |  |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 38 | 38 |  |  |  |  |
|  | Hamsters (Mesocricetus ) | 0 |  |  |  |  |  |
| 1.e. | Other Rodents (other Rodentia) | 18 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 533 | 533 |  |  |  | 466 |
| 1.g. | Cats (Felis catus) | 0 |  |  |  |  |  |
| 1.h. | Dogs (Canis familiaris) | 15 | 15 |  |  |  | 6 |
| 1.i. | Ferrets (Mustela putorius furo) | 0 |  |  |  |  |  |
| 1.j. | Other Carnivores (other Carnivora) | 0 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 1 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 16 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 0 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 57 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 0 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 |  |  |  |  |  |
| 1.q. | New World Monkeys (Ceboidea) | 0 |  |  |  |  |  |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 0 |  |  |  |  |  |
| 1.s. | Apes (Hominoidea) | 0 |  |  |  |  |  |
| 1.t. | Other Mammals (other Mammalia) | 0 |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 0 |  |  |  |  |  |
| 1.v. | Other birds (other Aves) | 22 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 3 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 0 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 0 |  |  |  |  |  |
| 1.z. | TOTAL | 11991 |  |  |  |  |  |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

## Purpose versus species

|  | $\begin{gathered} \hline 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 <br> Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8 <br> Education and <br> training | $\begin{gathered} 2.9 \\ \text { Other } \end{gathered}$ | $\begin{gathered} \hline 2.10 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 760 | 2157 | 4467 | 240 | 478 | 334 | 104 | 16 | 8556 |
| 2.b. | Rats | 1087 | 293 | 743 |  | 497 |  | 112 |  | 2732 |
| 2.c. | Guinea-Pigs | 22 |  |  |  |  | 9 | 7 |  | 38 |
| 2.d. | Hamsters |  |  |  |  |  |  |  |  |  |
| 2.e. | Other Rodents |  |  |  |  |  | 16 | 2 |  | 18 |
| 2.f. | Rabbits |  |  | 466 |  | 45 | 1 | 21 |  | 533 |
| 2.g. | Cats |  |  |  |  |  |  |  |  |  |
| 2.h. | Dogs | 7 |  |  |  |  |  | 2 | 6 | 15 |
| 2.i. | Ferrets |  |  |  |  |  |  |  |  |  |
| 2.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |
| 2.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 1 |  | 1 |
| 2.1. | Pigs |  |  |  |  |  |  | 16 |  | 16 |
| 2.m. | Goats |  |  |  |  |  |  |  |  |  |
| 2.n. | Sheep | 5 |  |  |  | 34 | 18 |  |  | 57 |
| 2.0. | Cattle |  |  |  |  |  |  |  |  |  |
| 2.p. | Prosimians |  |  |  |  |  |  |  |  |  |
| 2.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |
| 2.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |
| 2.s. | Apes |  |  |  |  |  |  |  |  |  |
| 2.t. | Other Mammals |  |  |  |  |  |  |  |  |  |
| 2.u. | Quail |  |  |  |  |  |  |  |  |  |
| 2.v. | Other birds | 7 |  |  |  |  |  | 15 |  | 22 |
| 2.w. | Reptiles |  |  |  |  |  |  | 3 |  | 3 |
| 2.x. | Amphibians |  |  |  |  |  |  |  |  |  |
| 2.y. | Fish |  |  |  |  |  |  |  |  |  |
| 2.z. | TOTAL | 1888 | 2450 | 5676 | 240 | 1054 | 378 | 283 | 22 | 11991 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Products versus species

|  | $\begin{gathered} \hline 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ <br> substances <br> used or <br> intended to <br> be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ <br> substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ <br> substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminants in the general environment which do not appear in other columns | 3.10 <br> Other toxicological or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 478 |  |  |  |  |  |  |  |  | 478 |
| 3.b. | Rats | 497 |  |  |  |  |  |  |  |  | 497 |
| 3.c. | Guinea-Pigs |  |  |  |  |  |  |  |  |  |  |
| 3.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |
| 3.e. | Other Rodents |  |  |  |  |  |  |  |  |  |  |
| 3.f. | Rabbits |  |  |  |  |  |  |  |  | 45 | 45 |
| 3.g. | Cats |  |  |  |  |  |  |  |  |  |  |
| 3.h. | Dogs |  |  |  |  |  |  |  |  |  |  |
| 3.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |
| 3.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |
| 3.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  |  |
| 3.1. | Pigs |  |  |  |  |  |  |  |  |  |  |
| 3.m. | Goats |  |  |  |  |  |  |  |  |  |  |
| 3.n. | Sheep | 34 |  |  |  |  |  |  |  |  | 34 |
| 3.0. | Cattle |  |  |  |  |  |  |  |  |  |  |
| 3.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |
| 3.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |  |
| 3.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |  |
| 3.s. | Apes |  |  |  |  |  |  |  |  |  |  |
| 3.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |
| 3.u. | Quail |  |  |  |  |  |  |  |  |  |  |
| 3.v. | Other birds |  |  |  |  |  |  |  |  |  |  |
| 3.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |
| 3.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |
| 3.y. | Fish |  |  |  |  |  |  |  |  |  |  |
| 3.z. | TOTAL | 1009 |  |  |  |  |  |  |  | 45 | 1054 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3 Human nervous and mental disorders | 4.4 <br> Human cancer (excluding evaluations of carcinogenic hazards or risks) | $\stackrel{4.5}{\text { Other human diseases }}$ | $4.6$ <br> Studies specific to animal diseases | $4.7$ <br> Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 99 |  |  | 426 |  | 525 |
| 4.b. | Rats | 323 | 735 |  | 157 |  | 1215 |
| 4.c. | Guinea-Pigs |  |  |  | 22 |  | 22 |
| 4.d. | Hamsters |  |  |  |  |  |  |
| 4.e. | Other Rodents |  |  |  | 16 |  | 16 |
| 4.f. | Rabbits |  |  |  |  |  |  |
| 4.g. | Cats |  |  |  |  |  |  |
| 4.h. | Dogs |  |  |  |  |  |  |
| 4.i. | Ferrets |  |  |  |  |  |  |
| 4.j. | Other Carnivores |  |  |  |  |  |  |
| 4.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |
| 4.1. | Pigs |  |  |  |  |  |  |
| 4.m. | Goats |  |  |  |  |  |  |
| 4.n. | Sheep |  |  |  | 8 |  | 8 |
| 4.0. | Cattle |  |  |  |  |  |  |
| 4.p. | Prosimians |  |  |  |  |  |  |
| 4.q. | New World Monkeys |  |  |  |  |  |  |
| 4.r. | Old World Monkeys |  |  |  |  |  |  |
| 4.s. | Apes |  |  |  |  |  |  |
| 4.t. | Other Mammals |  |  |  |  |  |  |
| 4.u. | Quail |  |  |  |  |  |  |
| 4.v. | Other birds |  |  |  |  |  |  |
| 4.w. | Reptiles |  |  |  |  |  |  |
| 4.x. | Amphibians |  |  |  |  |  |  |
| 4.y. | Fish |  |  |  |  |  |  |
| 4.z. | TOTAL | 422 | 735 |  | 629 |  | 1786 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} \hline 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 5.4 Member Country of Council of Europe (but not EC) legislation 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice |  | 4707 |  |  |  |  | 4707 |
| 5.b. | Rats |  | 743 |  |  |  |  | 743 |
| 5.c. | Guinea-Pigs |  |  |  |  |  |  |  |
| 5.d. | Hamsters |  |  |  |  |  |  |  |
| 5.e. | Other Rodents |  |  |  |  |  |  |  |
| 5.f. | Rabbits |  | 466 |  |  |  |  | 466 |
| 5.g. | Cats |  |  |  |  |  |  |  |
| 5.h. | Dogs |  |  |  |  |  |  |  |
| 5.i. | Ferrets |  |  |  |  |  |  |  |
| 5.j. | Other Carnivores |  |  |  |  |  |  |  |
| 5.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |
| 5.1. | Pigs |  |  |  |  |  |  |  |
| 5.m. | Goats |  |  |  |  |  |  |  |
| 5.n. | Sheep |  |  |  |  |  |  |  |
| 5.0. | Cattle |  |  |  |  |  |  |  |
| 5.p. | Prosimians |  |  |  |  |  |  |  |
| 5.q. | New World Monkeys |  |  |  |  |  |  |  |
| 5.r. | Old World Monkeys |  |  |  |  |  |  |  |
| 5.s. | Apes |  |  |  |  |  |  |  |
| 5.t. | Other Mammals |  |  |  |  |  |  |  |
| 5.u. | Quail |  |  |  |  |  |  |  |
| 5.v. | Other birds |  |  |  |  |  |  |  |
| 5.w. | Reptiles |  |  |  |  |  |  |  |
| 5.x. | Amphibians |  |  |  |  |  |  |  |
| 5.y. | Fish |  |  |  |  |  |  |  |
| 5.z. | TOTAL |  | 5916 |  |  |  |  | 5916 |

Examples:
5.2 - France is testing due to a UK (or FR) specific requirement
5.3- UK is testing according to EC legislation
5.4 - Spain is testing due to a Hungarian requirement
5.5 - Sweden is testing due to a US specific requirement
5.6 - Germany is testing due to a Czech requirement (also an EC

Note: columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

## TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 National legislation specific to a single EC Member State 1) | 6.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 6.4 <br> Member Country of Council <br> of Europe (but not EC) <br> legislation <br> 2) | $\begin{gathered} 6.5 \\ \text { Other legislation } \end{gathered}$ | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | 6.7 <br> No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice |  | 478 |  |  |  |  | 478 |
| 6.b. | Rats |  | 487 |  |  | 0 | 10 | 497 |
| 6.c. | Guinea-Pigs |  |  |  |  |  |  | 0 |
| 6.d. | Hamsters |  |  |  |  |  |  | 0 |
| 6.e. | Other Rodents |  |  |  |  |  | 45 | 45 |
| 6.f. | Rabbits |  |  |  |  |  |  | 0 |
| 6.g. | Cats |  |  |  |  |  |  | 0 |
| 6.h. | Dogs |  |  |  |  |  |  | 0 |
| 6.i. | Ferrets |  |  |  |  |  |  | 0 |
| 6.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 6.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 6.1. | Pigs |  |  |  |  |  |  | 0 |
| 6.m | Goats |  |  |  |  |  | 34 | 34 |
| 6.n. | Sheep |  |  |  |  |  |  | 0 |
| 6.0. | Cattle |  |  |  |  |  |  | 0 |
| 6.p. | Prosimians |  |  |  |  |  |  | 0 |
| 6.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 6.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
| 6.s. | Apes |  |  |  |  |  |  | 0 |
| 6.t. | Other Mammals |  |  |  |  |  |  | 0 |
| 6.u. | Quail |  |  |  |  |  |  | 0 |
| 6.v. | Other birds |  |  |  |  |  |  | 0 |
| 6.w | Reptiles |  |  |  |  |  |  | 0 |
| 6.x. | Amphibians |  |  |  |  |  |  | 0 |
| 6.y. | Fish |  |  |  |  |  |  | 0 |
| 6.z. | TOTAL |  | 965 | 0 | 0 | 0 | 89 | 1054 |
| Examples: 6.2 - France is testing due to a UK (or FR) specific requirement <br>  6.3 - UK is testing according to EC legislation <br>  6.4 - Spain is testing due to a Hungarian requirement <br>  6.5 - Sweden is testing due to a US specific requirement <br>  6.6 - Germany is testing due to a Czech requirement (also an EC <br>  requirement) |  |  |  | Example: a test required by French legisla ISO protocol must be coded as a entered into column 6.2 in the ta |  | imposing that the tes tual test method, guid d carried out in Belgi al (FR) legislative req bmitted by Belgium. | carried out and or protocol. ccording to an nent and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| 7.1 Species |  | 7.2Acute and sub-acute toxicity testing methods(including limit test) |  |  | $\begin{array}{c\|} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{array}$ | 7.4 Skin sensitisatio n | 7.5 Eye irritation | 7.6 Sub- chronic and chronic toxicity | 7.7 <br> Carcinogenicity | 7.8 <br> Developmental toxicity | 7.9 Muta- genicit $y$ | 7.10 <br> Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{gathered} \hline 7.12 \\ \text { Other } \end{gathered}$ | $\begin{gathered} \hline 7.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 478 |  |  |  |  |  |  |  |  |  |  |  |  | 478 |
| 7.b. | Rats | 487 |  |  |  |  |  |  |  |  |  |  |  | 10 | 497 |
| 7.c. | Guinea-Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.e. | Other Rodents |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.f. | Rabbits |  |  |  |  |  |  |  |  |  |  |  |  | 45 | 45 |
| 7.g. | Cats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.h. | Dogs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.1. | Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.m. | Goats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.n. | Sheep |  |  |  |  |  |  |  |  |  |  |  |  | 34 | 34 |
| 7.0. | Cattle |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.s. | Apes |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.u. | Quail |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.v. | Other birds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.y. | Fish |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.z. | TOTAL | 965 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 89 | 1054 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products

| $\begin{gathered} 8.1 \\ \text { Products } \end{gathered}$ | 8.2Acute and sub-acute toxicity testing <br> methods (including limit test) |  |  | $\begin{gathered} \hline 8.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 8.4 Skin sensitisatio n | 8.5 Eye irritation |  | $8.7$ <br> Carcino genicity | $8.8$ <br> Developmental toxicity | $\begin{gathered} 8.9 \\ \text { Muta- } \\ \text { genicit } \\ y \end{gathered}$ | 8.10 <br> Reproductive toxicity | 8.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 8.12 \\ & \text { Other } \end{aligned}$ | $\begin{gathered} \hline 8.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine | 965 |  |  |  |  |  |  |  |  |  |  |  | 34 | 999 |
| 8.b. $\begin{aligned} & \text { Products/substances used or intended to } \\ & \text { be used mainly in agriculture }\end{aligned}$ |  |  |  |  |  |  |  |  |  |  | 55 |  |  | 55 |
| 8.c. $\begin{aligned} & \text { Products/substances used or intended to } \\ & \text { be used mainly in industry }\end{aligned}$ |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.d. Products/substances used or intended to be used mainly in the household |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.f. Products/substances used or intended to be used mainly as additives in food for human consumption |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.g.Products/substances used or intended to <br> be used mainly as additives in food for <br> animal consumption |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.i. Other toxicological or safety evaluations |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.j. TOTAL | 965 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 55 | 0 | 34 | 1054 |

## SLOVAKIA

## Statistical data submitted

The statistical data have been submitted by the State Veterinary and Food Administration of the Slovak Republic, Botanická 17, 84213 Bratislava

## Comments of Slovakian authorities

National comments to the statistical evaluation of data concerning the number of experimental animals used in experiments in the year 2005 in the Slovak Republic.

The State Veterinary and Food Administration of the Slovak Republic (hereinafter "SVFA SR") as a competent authority of the Slovak Republic in the matter of approval of establishments for breeding and use of animals for experimental and other scientific purposes is comprised of $\mathbf{8}$ Regional Veterinary and Food Administrations (hereinafter RVFA) and 40 District Veterinary and Food Administrations (hereinafter DVFA). All the workers of the veterinary administration in the field of animal welfare are veterinarians.

The SVFA SR approves in compliance with Article 6 of the Act No.488/2002 Coll. on Veterinary Care and on Amendment to Some Laws as later amended ( hereinafter Act No. 488/2002 Coll.) and in compliance with Article 7 and Article 13 and 17 of the Ordinance of the Government of Slovak Republic No. 289/2003 Coll., laying down requirements for the protection of animals used for experimental purposes or other scientific purposes as later amended (hereinafter "Ordinance of the Government of the Slovak Republic No. 289/2003 Coll.".), experimental, breeding and supplying establishments and all the experiments performed using animals. Each approved establishment is kept by the SVFA SR on the list of approved establishments on the website of SVFA SR www.svssr.sk. in compliance with Article 37 of the Act No. 488/2002 Coll.

Approval of all kinds of establishments is performed by the SVFA SR based on affirmative standpoint on assessment of the suitability of establishment for housing, breeding, care and the use of animals for experiments, issued by the RVFA) in compliance with Article 12 and 16 of the Ordinance of the Government of the Slovak Republic No.289/2003 Coll. The RVFA issues a standpoint based on results of a control performed directly in the establishment for the purpose of assessment of observance of requirements for approved establishment, which are laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. Controls of establishments are performed by veterinarians - RVFA animal welfare inspectors. Animal welfare inspectors shall be obliged, in compliance with Article 7 of the Act 488/2002 Coll. and Article 21 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. to perform minimum once a year non-discriminatory controls of all approved establishments for the purpose of control of observance of requirements for approved establishment which are laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. The SVFA SR, as a competent authority, trained theoretically and also practically all the animal welfare
inspectors for the performance of the control. Controls are performed based on methodical instructions and check lists worked out by the competent authority in compliance with requirements laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. and in the Act 488/2002 Coll.

The SVFA SR approved in the year 2005, based on applicant's applications a total of 7 new experimental establishments, 1 breeding establishment for breeding of experimental animals.

Total number of establishments in the Slovak Republic in the year 2005

| Kind of establishment | Number |
| :--- | :---: |
| Experimental establishment | 43 |
| Experimental establishment with breeding <br> of animals for own use | 20 |
| Breeding establishment | 7 |
| Supplying establishment | 1 |
| Total: | $\mathbf{7 1}$ |

The SVFA SR approves the experiments performed upon animals based on the application for approval of the experiment submitted by an applicant - approved experimental establishment. Each application for approval of an experiment shall be submitted by an applicant in compliance with Article 20 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. in order to be judged by the ETHIC COMMISSION. Each approved experimental establishment shall have established its own ethic commission comprised of minimum 5 members, out of which $1 / 3$ must not be dependent from the experimental establishment. Ethic commission, on the submitted project of an experiment, shall assess justification of each experiment, use of the animals in the experiment and specification of species and number of animals in the experiment. An applicant may submit his/her project of an experiment for approval by the SVFA SR only after recommendation for submission, issued by the ethic commission. The SVFA SR has in compliance with the Act No. 71/1967 Coll. On Administrative Proceedings (Administrative Codex) minimum 30 days for assessment of an application for approval of the experiment. The SVFA SR. as a competent authority shall issue a decision by which the performance of the experiment may be approved or refused. In approval of the experiment, the SVFA SR shall assess the conformity of purpose of the experiment (3R), methods of performance of the experiment, origin of experimental animals, handling, care and housing of experimental animals with provision laid down in the Ordinance of the Government No. 289/2003 Coll., in compliance with the valid legislation in the Slovak Republic and in the European Union. The SVFA SR established, based on the Article 8 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. advisory body of the chief veterinary officer the members of which are scientific workers in the said branch. The SVFA SR in case of the need of professional consultation concerning the aim of the experiment, the need of use of the animals in
the experiment and the number of used animals shall ask the members of the advisory body for opinion - to the submitted application for approval of the experiment- with observance of rules of personal data protection and protection of data with signs of trade secret or intellectual property.

To the Table No. 1 most of experimental animals originate in domestic breeding establishments or in experimental establishments with breeding of animals for own use. As far as foreign suppliers are concerned, the animals originate mainly in the Czech Republic, Hungary, Germany, Poland and France.

To the Table No. 2 The SVFA SR approved 273 experiments with use of experimental animals and suspended the proceeding in 10 applications for approval of the experiment in the year 2005. The total number of used animals does not reflect the number of approved experiments, because in number of used experimental animals also the animals are included which were used in the year 2005 from the experiments, approved in the year 2003, 2004 for the period of 2-3 years. In the column 2.8, in total 7 experiments as pre-experiments for introduction of surgical methods and practices in the course of performance of main experiments were approved.

Number of approved experiments in the Slovak Republic for the year 2005
Dividing of experiments based on the Table No. 2 (number of animals used in the experiment for a various purpose) from the statistical notification of the number of used animals

| Kind of experiment- purpose of the <br> experiment | Number of experiments performed |
| :--- | :---: |
| 2.2. Basic research | 70 |
| 2.3. Research and development of <br> products and devices for human medicine <br> and veterinary medicine and dentistry | 79 |
| 2.4. Production and control of quality of <br> products and devices for human medicine <br> and dentistry | 5 |
| 2.5. Production and control of quality of <br> products and devices for veterinary <br> medicine |  |
| 2.6. Toxicological and other safety <br> evaluations including evaluation of safety <br> of products and devices for human and <br> veterinary medicine and dentistry | 10 |
| 2.7. Disease diagnostics | 62 |


| 2.8. Education and training | 7 |
| :--- | :---: |
| 2.9. Other | 15 |
| Total | $\mathbf{2 7 3}$ |

To the Table No. 3 In the column 3.2 most animals were used for evaluation of products and substances for human medicine. In the column 3.3 the animal was used for control of products/substances used in agriculture- mainly pesticide, herbicide products. In the column 3.4 the animals used for control of various chemical products/ substances being a part of oils, lubricants and rude materials are indicated.

To the Table No. 4 Explanation to the column 4.5. Animals were used for the purpose of investigation of immune systems, infectious diseases, and metabolism disorders in man and in the column 4.6 in animals.

To the Table No. 5 In the Slovak Republic the experiments upon animals are performed in compliance with the valid Slovak legislation, in which the legal acts of the European Communities and the European Union are incorporated. The experiments are performed in compliance with the valid legislation of the European Pharmacopoeia, in the column 5.5 the experiments were performed according to the valid national legislation e.g. STN EN ISO standards. In the column 5.7 the methods in control of human products/substances were used that were created by the experimental establishment as a modified method based on the approved pharmacopoeial methods or as a new individual method.

To the Table No. 6 The Slovak Republic has elaborated the valid legislation for the control of drugs - Act No. 140/1998 Coll. Act On Medicinal Products and Medical Devices as amended, for the control of chemical substances and preparations the Act No. 163/2001 Coll. On Chemical Substances and Preparations, Decree of the Ministry of Economy No. 2/2005 Annex 5 Part B Methods B, that are analogous to OECD methods. In the column 6.3 the number of animals used in compliance with the European Pharmacopoeia are indicated, in the column 6.4 a total of 4 rabbits were used in the experiment of eye irritation in control of a substance used mainly in agriculture.

To the Table No. 7 In the column7.2.1. the animals were used only in limit test. Tests were performed mainly by methods OECD TG 402, 403. In the column 7.2.2. the tests OECD TG 423, B. 1 tris were performed. In the column 7.2 .3 mainly tests in compliance with OECD TG 407, 420, tolerance studies were performed.

In compliance with Article 17 para 4 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. each approved establishment shall be obliged, in order to maintain the approval, to submit yearly by the end of January for the previous year to the SVFA SR a notification on the form according to the specimen laid down in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. on the number of used animals. Approved establishments shall be obliged to keep records about the number of used GMO animals in the experiment. Based on collected data the SVFA SR shall yearly work out a notification about the activity of the SVFA SR in which the numbers of approved establishments and approved or refused
experiments as well as numbers and species of used animals in the experiment for the respective year are published.

Controls of establishments are performed by veterinarians - RVFA animal welfare inspectors. Animal welfare inspectors shall be obliged, in compliance with Article 7 of the Act 488/2002 Coll. And Article 21 of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. to perform minimum once a year nondiscriminatory controls of all approved establishments for the purpose of control of observance of requirements for approved establishment indicated in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. The SVFA, as a competent authority, has trained theoretically and also practically all the animal welfare inspectors for performance of the control. Controls are performed based on methodical instructions and check lists worked out by the competent authority in compliance with requirements indicated in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. and in the Act 488/2002 Coll.

Control of animal welfare in approved establishments is performed by animal welfare inspectors - veterinarians in compliance with Article 8 para 3 letter b) and Article 21 of the Act No. 488/2002 Coll. and of the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. Controls of animal welfare are non-discriminatory, performed minimum once a year in each approved establishment. The competent authority trained all the inspectors for performance of animal welfare inspection and worked out the methodical instruction according to which the animal welfare inspections are performed. The purpose of animal welfare control in approved establishments is a control of observance of requirements laid down in the Act No. 488/2002 Coll, Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. Animal welfare inspectors shall control conformity of the test performance in an approved experimental establishment with a decision issued by the SVFA SR on the approval of the experiment. Finding of infringements laid down in the Act No. 488/2002 Coll., Article 21 and 44 and in the Ordinance of the Government of the Slovak Republic No. 289/2003 Coll. is classified as an administrative delict for which a penalty may be imposed on a legal or natural person in compliance with Article 45 of the Act No. 488/2002 Coll.

The SVFA SR performs theoretical and practical trainings of all workers of veterinary administration in performance of control with regard to housing, care and protection of experimental animals.

The competent authority performs consulting services for public in the field of animal welfare, organizes trainings for workers of approved establishments the purpose of which is interpretation of the valid legislation of the Slovak Republic in the field of animal welfare. The SVFA SR organizes also seminars and lectures aimed at protection of experimental animals used for experimental purposes. In compliance with the Article 35 of the Act. No. 488/2002 Coll. the animal owner, keeper and dealer shall be obliged to educate demonstrably the persons handling the animals so that such persons must avoid from any acts that might cause injury or any other damage to the health of animals or unnecessary suffering thereof.

Prof. Jozef Bíreš, DVM, DrSc, Chief Veterinary Officer

## TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

## Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | $\begin{gathered} \hline 1.7 \\ \text { Re-used animals } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Mice (Mus musculus) | 14975 | 9246 |  | 5729 |  |  |
| 1.b. | Rats (Rattus norvegicus) | 6761 | 4942 | 51 | 1768 |  |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 594 | 514 |  | 80 |  |  |
| 1.d. | Hamsters (Mesocricetus ) | 0 |  |  |  |  |  |
| 1.e. | Other Rodents (other Rodentia) |  |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 782 | 632 |  | 150 |  | 126 |
| 1.g. | Cats (Felis catus) | 0 |  |  |  |  |  |
| 1.h. | Dogs (Canis familiaris) | 6 |  |  | 6 |  |  |
| 1.i. | Ferrets (Mustela putorius furo) | 0 |  |  |  |  |  |
| 1.j. | Other Carnivores (other Carnivora) |  |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) |  |  |  |  |  |  |
| 1.1. | Pigs (Sus) |  |  |  |  |  |  |
| 1.m. | Goats (Capra) |  |  |  |  |  |  |
| 1.n. | Sheep (Ovis) |  |  |  |  |  |  |
| 1.0. | Cattle (Bos) |  |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 |  |  |  |  |  |
| 1.q. | New World Monkeys (Ceboidea) | 0 |  |  |  |  |  |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 0 |  |  |  |  |  |
| 1.s. | Apes (Hominoidea) | 0 |  |  |  |  |  |
| 1.t. | Other Mammals (other Mammalia) |  |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 251 | 251 |  |  |  |  |
| 1.v. | Other birds (other Aves) |  |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) |  |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) |  |  |  |  |  |  |
| 1.y. | Fish (Pisces) |  |  |  |  |  |  |
| 1.z. | TOTAL | 23369 |  |  |  |  |  |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

## Purpose versus species

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 7415 | 2433 | 117 | 482 | 440 | 3766 | 100 | 222 | 14975 |
| 2.b. | Rats | 4857 | 341 |  |  | 1015 | 292 | 50 | 206 | 6761 |
| 2.c. | Guinea-Pigs | 252 | 122 | 116 |  | 84 |  | 3 | 17 | 594 |
| 2.d. | Hamsters |  |  |  |  |  |  |  |  | 0 |
| 2.e. | Other Rodents |  |  |  |  |  |  |  |  | 0 |
| 2.f. | Rabbits | 133 | 39 | 161 | 91 | 159 | 178 | 3 | 18 | 782 |
| 2.g. | Cats |  |  |  |  |  |  |  |  | 0 |
| 2.h. | Dogs |  |  |  |  | 6 |  |  |  | 6 |
| 2.i. | Ferrets |  |  |  |  |  |  |  |  | 0 |
| 2.j. | Other Carnivores |  |  |  |  |  |  |  |  | 0 |
| 2.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  | 0 |
| 2.1. | Pigs |  |  |  |  |  |  |  |  | 0 |
| 2.m. | Goats |  |  |  |  |  |  |  |  | 0 |
| 2.n. | Sheep |  |  |  |  |  |  |  |  | 0 |
| 2.0. | Cattle |  |  |  |  |  |  |  |  | 0 |
| 2.p. | Prosimians |  |  |  |  |  |  |  |  | 0 |
| 2.q. | New World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.r. | Old World Monkeys |  |  |  |  |  |  |  |  | 0 |
| 2.s. | Apes |  |  |  |  |  |  |  |  | 0 |
| 2.t. | Other Mammals |  |  |  |  |  |  |  |  | 0 |
| 2.u. | Quail |  |  |  |  |  |  |  |  | 0 |
| 2.v. | Other birds | 251 |  |  |  |  |  |  |  | 251 |
| 2.w. | Reptiles |  |  |  |  |  |  |  |  | 0 |
| 2.x. | Amphibians |  |  |  |  |  |  |  |  | 0 |
| 2.y. | Fish |  |  |  |  |  |  |  |  | 0 |
| 2.z. | TOTAL | 12908 | 2935 | 394 | 573 | 1704 | 4236 | 156 | 463 | 23369 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Products versus species

|  | $\begin{gathered} \hline 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ <br> substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminants in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 270 | 50 | 120 |  |  |  |  |  |  | 440 |
| 3.b. | Rats | 296 | 121 | 514 |  |  | 6 | 75 |  | 3 | 1015 |
| 3.c. | Guinea-Pigs | 84 |  |  |  |  |  |  |  |  | 84 |
| 3.d. | Hamsters |  |  |  |  |  |  |  |  |  | 0 |
| 3.e. | Other Rodents |  |  |  |  |  |  |  |  |  | 0 |
| 3.f. | Rabbits | 66 | 10 | 71 |  |  |  | 9 |  | 3 | 159 |
| 3.g. | Cats |  |  |  |  |  |  |  |  |  | 0 |
| 3.h. | Dogs | 6 |  |  |  |  |  |  |  |  | 6 |
| 3.i. | Ferrets |  |  |  |  |  |  |  |  |  | 0 |
| 3.j. | Other Carnivores |  |  |  |  |  |  |  |  |  | 0 |
| 3.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  | 0 |
| 3.1. | Pigs |  |  |  |  |  |  |  |  |  | 0 |
| 3.m. | Goats |  |  |  |  |  |  |  |  |  | 0 |
| 3.n. | Sheep |  |  |  |  |  |  |  |  |  | 0 |
| 3.0. | Cattle |  |  |  |  |  |  |  |  |  | 0 |
| 3.p. | Prosimians |  |  |  |  |  |  |  |  |  | 0 |
| 3.q. | New World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.s. | Apes |  |  |  |  |  |  |  |  |  | 0 |
| 3.t. | Other Mammals |  |  |  |  |  |  |  |  |  | 0 |
| 3.u. | Quail |  |  |  |  |  |  |  |  |  | 0 |
| 3.v. | Other birds |  |  |  |  |  |  |  |  |  | 0 |
| 3.w. | Reptiles |  |  |  |  |  |  |  |  |  | 0 |
| 3.x. | Amphibians |  |  |  |  |  |  |  |  |  | 0 |
| 3.y. | Fish |  |  |  |  |  |  |  |  |  | 0 |
| 3.z. | TOTAL | 722 | 181 | 705 | 0 | 0 | 6 | 84 | 0 | 6 | 1704 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3 Human nervous and mental disorders | 4.4 <br> Human cancer (excluding evaluations of carcinogenic hazards or risks) | $\stackrel{4.5}{\text { Other human diseases }}$ | $4.6$ <br> Studies specific to animal diseases | $\begin{gathered} \hline 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 29 | 2787 | 623 | 8677 | 1497 | 13613 |
| 4.b. | Rats | 1944 | 1573 | 181 | 1792 |  | 5490 |
| 4.c. | Guinea-Pigs | 38 |  |  | 336 |  | 374 |
| 4.d. | Hamsters |  |  |  |  |  | 0 |
| 4.e. | Other Rodents |  |  |  |  |  | 0 |
| 4.f. | Rabbits |  | 59 | 8 | 283 |  | 350 |
| 4.g. | Cats |  |  |  |  |  | 0 |
| 4.h. | Dogs |  |  |  |  |  | 0 |
| 4.i. | Ferrets |  |  |  |  |  | 0 |
| 4.j. | Other Carnivores |  |  |  |  |  | 0 |
| 4.k. | Horses, donkeys and cross breds |  |  |  |  |  | 0 |
| 4.1. | Pigs |  |  |  |  |  | 0 |
| 4.m. | Goats |  |  |  |  |  | 0 |
| 4.n. | Sheep |  |  |  |  |  | 0 |
| 4.0. | Cattle |  |  |  |  |  | 0 |
| 4.p. | Prosimians |  |  |  |  |  | 0 |
| 4.q. | New World Monkeys |  |  |  |  |  | 0 |
| 4.r. | Old World Monkeys |  |  |  |  |  | 0 |
| 4.s. | Apes |  |  |  |  |  | 0 |
| 4.t. | Other Mammals |  |  |  |  |  | 0 |
| 4.u. | Quail |  |  |  |  |  | 0 |
| 4.v. | Other birds |  |  |  | 251 |  | 251 |
| 4.w. | Reptiles |  |  |  |  |  | 0 |
| 4.x. | Amphibians |  |  |  |  |  | 0 |
| 4.y. | Fish |  |  |  |  |  | 0 |
| 4.z. | TOTAL | 2011 | 4419 | 812 | 11339 | 1497 | 20078 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 EC legislation including European Pharmacopoeia (requirements) | 5.4 Member Country of Council of Europe (but not EC) legislation 2) | 5.5 Other legislation | 5.6 Any combination of $5.2 / 5.3 / 5.4 / 5.5$ | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice |  | 460 |  | 77 |  | 62 | 599 |
| 5.b. | Rats |  |  |  |  |  |  | 0 |
| 5.c. | Guinea-Pigs |  |  |  | 116 |  |  | 116 |
| 5.d. | Hamsters |  |  |  |  |  |  | 0 |
| 5.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 5.f. | Rabbits |  | 107 |  |  | 5 | 140 | 252 |
| 5.g. | Cats |  |  |  |  |  |  | 0 |
| 5.h. | Dogs |  |  |  |  |  |  | 0 |
| 5.i. | Ferrets |  |  |  |  |  |  | 0 |
| 5.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 5.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 5.1. | Pigs |  |  |  |  |  |  | 0 |
| 5.m. | Goats |  |  |  |  |  |  | 0 |
| 5.n. | Sheep |  |  |  |  |  |  | 0 |
| 5.0. | Cattle |  |  |  |  |  |  | 0 |
| 5.p. | Prosimians |  |  |  |  |  |  | 0 |
| 5.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 5.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
| 5.s. | Apes |  |  |  |  |  |  | 0 |
| 5.t. | Other Mammals |  |  |  |  |  |  | 0 |
| 5.u. | Quail |  |  |  |  |  |  | 0 |
| 5.v. | Other birds |  |  |  |  |  |  | 0 |
| 5.w. | Reptiles |  |  |  |  |  |  | 0 |
| 5.x. | Amphibians |  |  |  |  |  |  | 0 |
| 5.y. | Fish |  |  |  |  |  |  | 0 |
| 5.z. | TOTAL | 0 | 567 | 0 | 193 | 5 | 202 | 967 |

Examples:
5.2 - France is testing due to a UK (or FR) specific requirement 5.3-UK is testing according to EC legislation
5.4 - Spain is testing due to a Hungarian requirement 5.5 - Sweden is testing due to a US specific requirement
5.6 - Germany is testing due to a Czech requirement (also an EC

Note: columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

## TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 National legislation specific to a single EC Member State 1) | 6.3 EC legislation including European Pharmacopoeia (requirements) | 6.4 <br> Member Country of Council <br> of Europe (but not EC) <br> legislation <br> 2) | $\begin{gathered} 6.5 \\ \text { Other legislation } \end{gathered}$ | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | 6.7 <br> No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice | 120 | 320 |  |  |  |  | 440 |
| 6.b. | Rats | 669 | 346 |  |  |  |  | 1015 |
| 6.c. | Guinea-Pigs |  | 84 |  |  |  |  | 84 |
| 6.d. | Hamsters |  |  |  |  |  |  | 0 |
| 6.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 6.f. | Rabbits | 89 | 66 | 4 |  |  |  | 159 |
| 6.g. | Cats |  |  |  |  |  |  | 0 |
| 6.h. | Dogs | 6 |  |  |  |  |  | 6 |
| 6.i. | Ferrets |  |  |  |  |  |  | 0 |
| 6.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 6.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 6.1. | Pigs |  |  |  |  |  |  | 0 |
| 6.m | Goats |  |  |  |  |  |  | 0 |
| 6.n. | Sheep |  |  |  |  |  |  | 0 |
| 6.0. | Cattle |  |  |  |  |  |  | 0 |
| 6.p. | Prosimians |  |  |  |  |  |  | 0 |
| 6.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 6.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
| 6.s. | Apes |  |  |  |  |  |  | 0 |
| 6.t. | Other Mammals |  |  |  |  |  |  | 0 |
| 6.u. | Quail |  |  |  |  |  |  | 0 |
| 6.v. | Other birds |  |  |  |  |  |  | 0 |
| 6.w | Reptiles |  |  |  |  |  |  | 0 |
| 6.x. | Amphibians |  |  |  |  |  |  | 0 |
| 6.y. | Fish |  |  |  |  |  |  | 0 |
| 6.z. | TOTAL | 884 | 816 | 4 | 0 | 0 | 0 | 1704 |
| Examples: 6.2 - France is testing due to a UK (or FR) specific requirement <br>  6.3 - UK is testing according to EC legislation <br>  6.4 - Spain is testing due to a Hungarian requirement <br>  6.5 - Sweden is testing due to a US specific requirement <br>  6.6 - Germany is testing due to a Czech requirement (also an EC <br>  requirement) |  |  |  | Example: a test required by French legisla ISO protocol must be coded as a entered into column 6.2 in the ta |  | imposing that the test tual test method, guide d carried out in Belgiu al (FR) legislative requ bmitted by Belgium. | carried out and or protocol. ccording to an nent and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2 <br> Acute and sub-acute toxicity testing methods (including limit test) |  |  | $\begin{gathered} \hline 7.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 7.4 Skin sensitisatio n | 7.5 Eye irritation | 7.6 Sub- chronic and chronic toxicity | $7.7$ <br> Carcinogenicity | 7.8 <br> Develop- <br> mental toxicity | 7.9 Muta- genicit y | 7.10 Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 7.12 \\ & \text { Other } \end{aligned}$ | $\begin{gathered} \hline 7.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 100 | 60 |  |  |  |  |  |  |  | 160 |  |  | 120 | 440 |
| 7.b. | Rats | 6 | 285 | 222 | 218 | 159 |  | 100 |  |  |  |  |  | 25 | 1015 |
| 7.c. | Guinea-Pigs |  |  | 4 |  | 80 |  |  |  |  |  |  |  |  | 84 |
| 7.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.e. | Other Rodents |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.f. | Rabbits |  |  | 43 | 16 |  | 88 |  |  |  |  |  |  | 12 | 159 |
| 7.g. | Cats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.h. | Dogs |  |  | 6 |  |  |  |  |  |  |  |  |  |  | 6 |
| 7.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.1. | Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.m. | Goats |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.n. | Sheep |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.0. | Cattle |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.q. | New World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.s. | Apes |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.u. | Quail |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.v. | Other birds |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.y. | Fish |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 7.z. | TOTAL | 106 | 345 | 275 | 234 | 239 | 88 | 100 | 0 | 0 | 160 | 0 | 0 | 157 | 1704 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products


## SWEDEN

## Statistical data submitted

The statistical data have been submitted by the National Board for Laboratory Animals.

## Comments of Swedish authorities

## Additional comments and remarks on the Swedish statistical records over used laboratory animals 2005.

The deadline for submitting the statistical records covering the use of laboratory animals during 2005 to the EU commission was in July 2006. Most researchers were prompt and submitted their reports in March, although some were as late as MayJune despite several reminders from the Swedish Animal Welfare Agency (SAWA).

## Electronical statistical form and database

During 2006 SAWA has developed an electronically statistical reporting form that will give the researcher a possibility to submit the statistical records electronically to a computer base. SAWA's goal is that this will make it easier for the researcher to submit the statistical records and also that it will give the authority an excellent opportunity to handle, analyze and present the statistical records more easily.

## 86/609/EEC Directive

According to the EU definition (directive 86/609/EEC) the number of laboratory animals used during 2005 in Sweden reached about 505 600. This is approx. a $12 \%$ increase (about 58000 animals) compared to 2004. Three kinds of animals were predominately used in animal experimentation, the mice, the rat and fish. Indeed, these three groups comprised about $90 \%$ of all laboratory animals used during 2005. The increase in the use of mice is probably due to increased use of genetically modified animals. The large number of fish used is mainly explained by tagging of fish in assessment studies. The increase in the use of mice as a laboratory animal is an ongoing trend that has been consistent during the last 10 year period.

Whereas, a clear decrease can be seen in the use of guinea pigs and rabbits throughout the 1990s, this may be due to new techniques of producing antibodies, using in vitro production instead of whole animals.

## Diagram 1.

Illustrating the use of laboratory animals in Sweden during 2005 according to the EU directive. Sorted in different reporting categories.


## Specific use of animals

As in previous years most laboratory animals were used in either fundamental biological research ( $43 \%$ ) or in development of product/devices (17\%) used in human or veterinary medicine. During 2005, $3 \%$ of the animals were used in toxicological research, and finally, less than $1 \%$ of the total numbers of laboratory animals were used for diagnosing diseases. The most common animals used in toxicological research are mice, rats and fish and to lesser extent dogs and rabbits. Mammals were mostly used in experiments concerning products/substances or devices relating to human medicine, dentistry and veterinary medicine, fish are mainly used in the evaluation of hazardous environmental substances.

## Reused animals

During 2005, 209 animals were reused in experiments according to the EU directive. This is a slight increase compared to 2004 when 168 animals were reused. Of the animals reused approx. $90 \%$ were dogs ( 150 animals). To a much lesser extent old world monkeys and rabbits were reused, 28 and 31 respectively.

## Tendencies in Sweden

From 1990 until 2002 the mean number of laboratory animals used in Sweden was about 315000 with the highest number 1994 (approx. 351000 ) and the lowest 1997 (267 000). From 2003-2005 there has been a large increase in the number of animals used. This is mainly due to the fact that tagging of fish for assessment studies has been included as an animal experiment. After discussions with the Swedish Board of Fisheries, SAWA decided to include tagging of fish as an animal experiment. The mean number during 2003-2005 is about 489000 animals where the mean number of tagged fish is approx. 160000.

The reasons behind these fluctuations during the last decade are hard to speculate about. It may just be due to natural fluctuations and/or reflect the status of high or low economy in Sweden. However, one clear tendency is the decrease of rats throughout the 1990s. In 1990 approx. 160000 rats were used according to the EU directive. Whereas, during the year 2005 the number of rats in experiments is down to 83000 , an almost $50 \%$ decrease. On the other hand, the use of mice as laboratory animals has
increased throughout the 1990s; this rise is probably due to the increased use of transgenic technique(s).

## Swedish definition

Apart from the information, Sweden also collects its own statistical data on other use of laboratory animals. According to Swedish legislation all use of animals, which have a scientific purpose, should be recorded. Therefore, this statistical data includes all animals used in behaviour studies, feeding trials or animals being euthanized for the use of their tissues and organs. During 2005 about 767000 animals were reported according to this definition. The dominating animals were bird, mice, rats, fish and pigs. This is an increase with nearly 208000 animals compared with the figures in the year 2004 and is mainly due to increased use of birds and fish. The increase in birds is due to a large behavioural study on hens and the use of roosters, i.e. comb from roosters for the production of hyaloronic acids. The reason behind the increase in fish is that the Swedish Board of Fisheries performed a large feeding study with the goal of increasing the survival of fish released from hatcheries.

## Fish assessment

Apart from the categories described above, Sweden also collects statistical records on fish used in assessment studies. That is fish that are caught by trawling, netting etc. During 2005 the number of fish in this category was approx. 6356000

Diagram 2. The use of laboratory animals in Sweden according to 86/609/EEC directive $40 \%$ (approx. 505000 ) and the Swedish definition $60 \%$ (approx. 767000 )


Transgenic animals
The Swedish statistical records do not separate the use of transgenic animals from other laboratory animals. In agreement with EU directive, Sweden does not regard breeding of transgenic stocks as an experiment in it self. However, it is regarded as an experiment when transgenic animals are used in experiments or when new transgenic strains are created.

## Conclusions

The overall impression is that the use of laboratory animals according to the EU directive shows an increase when comparing the year 2005 with the numbers used during 2004. The effect(s) is most obviously when comparing the use of animals by the universities and other authorities. This is probably due to the fact that the new animal facilities where ready and in full operation during 2005 and of course the tagging of fish. During the same period the Swedish pharmaceutical industries also show a slight increase in the use of laboratory animals (approx: 7000 animals). The reason behind these fluctuations difficult speculate about it may just be a fact of natural fluctuations.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN

## Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} \hline 1.2 \\ \text { Total } \end{gathered}$ | 1.3 <br> Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
|  | Mice (Mus musculus) | 213727 | 152004 | 58954 | 0 | 2769 |  |
| 1.b. | Rats (Rattus norvegicus) | 83321 | 51536 | 31692 | 0 | 93 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 2014 | 1923 | 91 | 0 | 0 |  |
| 1.d. | Hamsters (Mesocricetus ) | 167 | 63 | 104 | 0 | 0 |  |
| 1.e. | Other Rodents (other Rodentia) | 1269 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 2112 | 1690 | 422 | 0 | 0 | 28 |
| 1.g. | Cats (Felis catus) | 220 | 175 | 0 | 0 | 45 | 0 |
| 1.h. | Dogs (Canis familiaris) | 1166 | 1035 | 47 | 0 | 84 | 150 |
| 1.i. | Ferrets (Mustela putorius furo) | 47 | 47 | 0 | 0 | 0 | 0 |
| 1.j. | Other Carnivores (other Carnivora) | 163 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 650 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 2722 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 23 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 256 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 727 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.q. | New World Monkeys (Ceboidea) | 12 | 12 | 0 | 0 | 0 | 0 |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 63 | 1 | 18 | 0 | 44 | 31 |
| 1.s. | Apes (Hominoidea) | 0 | 0 | 0 | 0 | 0 | 0 |
| 1.t. | Other Mammals (other Mammalia) | 639 |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 0 | 0 | 0 | 0 | 0 |  |
| 1.v. | Other birds (other Aves) | 7838 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 0 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 5496 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 183049 |  |  |  |  |  |
| 1.z. | TOTAL | 505681 |  |  |  |  |  |

 those countries has to be used when filling in this column.

Note 2: Only the white boxes need to be completed.
Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

## Purpose versus species

|  | $\begin{gathered} \hline 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6 ) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 152796 | 54941 | 68 | 54 | 2246 | 65 | 1128 | 2429 | 213727 |
| 2.b. | Rats | 47396 | 30220 | 80 | 0 | 4460 | 0 | 943 | 222 | 83321 |
| 2.c. | Guinea-Pigs | 578 | 956 | 443 | 17 | 0 | 0 | 6 | 14 | 2014 |
| 2.d. | Hamsters | 53 | 104 | 0 | 0 | 0 | 0 | 10 | 0 | 167 |
| 2.e. | Other Rodents | 401 | 868 | 0 | 0 | 0 | 0 | 0 | 0 | 1269 |
| 2.f. | Rabbits | 1053 | 472 | 46 | 2 | 347 | 2 | 35 | 155 | 2112 |
| 2.g. | Cats | 138 | 9 | 0 | 0 | 0 | 51 | 0 | 22 | 220 |
| 2.h. | Dogs | 370 | 317 | 0 | 0 | 441 | 15 | 3 | 20 | 1166 |
| 2.i. | Ferrets | 47 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 47 |
| 2.j. | Other Carnivores | 71 | 0 | 0 | 0 | 0 | 0 | 0 | 92 | 163 |
| 2.k. | Horses, donkeys and cross breds | 13 | 0 | 0 | 0 | 0 | 7 | 570 | 60 | 650 |
| 2.1. | Pigs | 1495 | 241 | 0 | 0 | 0 | 260 | 375 | 351 | 2722 |
| 2.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 23 | 23 |
| 2.n. | Sheep | 132 | 27 | 0 | 0 | 0 | 0 | 1 | 96 | 256 |
| 2.0. | Cattle | 315 | 33 | 0 | 0 | 0 | 29 | 340 | 10 | 727 |
| 2.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.q. | New World Monkeys | 0 | 0 | 0 | 0 | 12 | 0 | 0 | 0 | 12 |
| 2.r. | Old World Monkeys | 52 | 11 | 0 | 0 | 0 | 0 | 0 | 0 | 63 |
| 2.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.t. | Other Mammals | 489 | 0 | 0 | 0 | 0 | 0 | 0 | 150 | 639 |
| 2.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.v. | Other birds | 5689 | 245 | 15 | 0 | 0 | 0 | 1011 | 878 | 7838 |
| 2.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 2.x. | Amphibians | 5419 | 77 | 0 | 0 | 0 | 0 | 0 | 0 | 5496 |
| 2.y. | Fish | 3146 | 0 | 0 | 0 | 8667 | 0 | 577 | 170659 | 183049 |
| 2.z. | TOTAL | 219653 | 88521 | 652 | 73 | 16173 | 429 | 4999 | 175181 | 505681 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Products versus species

|  | $\begin{gathered} \hline 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ <br> substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminants in the general environment which do not appear in other columns | 3.10 Other toxico- logical or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 1042 | 0 | 0 | 0 | 0 | 0 | 0 | 159 | 1045 | 2246 |
| 3.b. | Rats | 4460 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4460 |
| 3.c. | Guinea-Pigs |  |  |  |  |  |  |  |  |  | 0 |
| 3.d. | Hamsters |  |  |  |  |  |  |  |  |  | 0 |
| 3.e. | Other Rodents |  |  |  |  |  |  |  |  |  | 0 |
| 3.f. | Rabbits | 347 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 347 |
| 3.g. | Cats |  |  |  |  |  |  |  |  |  | 0 |
| 3.h. | Dogs | 441 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 441 |
| 3.i. | Ferrets |  |  |  |  |  |  |  |  |  | 0 |
| 3.j. | Other Carnivores |  |  |  |  |  |  |  |  |  | 0 |
| 3.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  | 0 |
| 3.1. | Pigs |  |  |  |  |  |  |  |  |  | 0 |
| 3.m. | Goats |  |  |  |  |  |  |  |  |  | 0 |
| 3.n. | Sheep |  |  |  |  |  |  |  |  |  | 0 |
| 3.0. | Cattle |  |  |  |  |  |  |  |  |  | 0 |
| 3.p. | Prosimians |  |  |  |  |  |  |  |  |  | 0 |
| 3.q. | New World Monkeys | 12 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 12 |
| 3.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  | 0 |
| 3.s. | Apes |  |  |  |  |  |  |  |  |  | 0 |
| 3.t. | Other Mammals |  |  |  |  |  |  |  |  |  | 0 |
| 3.u. | Quail |  |  |  |  |  |  |  |  |  | 0 |
| 3.v. | Other birds |  |  |  |  |  |  |  |  |  | 0 |
| 3.w. | Reptiles |  |  |  |  |  |  |  |  |  | 0 |
| 3.x. | Amphibians |  |  |  |  |  |  |  |  |  | 0 |
| 3.y. | Fish | 0 | 300 | 0 | 0 | 0 | 0 | 0 | 8367 | 0 | 8667 |
| 3.z. | TOTAL | 6302 | 300 | 0 | 0 | 0 | 0 | 0 | 8526 | 1045 | 16173 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  | $\begin{gathered} \hline 4.1 \\ \text { Species } \end{gathered}$ | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 <br> Studies specific to animal diseases | $\begin{gathered} \hline 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 33843 | 27196 | 30212 | 81523 | 19919 | 192693 |
| 4.b. | Rats | 2877 | 6771 | 27216 | 39155 | 0 | 76019 |
| 4.c. | Guinea-Pigs | 0 | 344 | 485 | 760 | 17 | 1606 |
| 4.d. | Hamsters | 0 | 66 | 0 | 91 | 0 | 157 |
| 4.e. | Other Rodents | 0 | 77 | 0 | 1192 | 0 | 1269 |
| 4.f. | Rabbits | 22 | 373 | 115 | 900 | 2 | 1412 |
| 4.g. | Cats | 0 | 0 | 52 | 0 | 145 | 197 |
| 4.h. | Dogs | 0 | 128 | 18 | 145 | 392 | 683 |
| 4.i. | Ferrets | 0 | 0 | 33 | 14 | 0 | 47 |
| 4.j. | Other Carnivores | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.k. | Horses, donkeys and cross breds | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.1. | Pigs | 0 | 534 | 0 | 978 | 370 | 1882 |
| 4.m. | Goats | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.n. | Sheep | 17 | 0 | 0 | 40 | 0 | 57 |
| 4.0. | Cattle | 0 | 10 | 0 | 0 | 358 | 368 |
| 4.p. | Prosimians | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.q. | New World Monkeys | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.r. | Old World Monkeys | 0 | 1 | 0 | 56 | 0 | 57 |
| 4.s. | Apes | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.t. | Other Mammals | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.u. | Quail | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.v. | Other birds | 0 | 0 | 0 | 80 | 545 | 625 |
| 4.w. | Reptiles | 0 | 0 | 0 | 0 | 0 | 0 |
| 4.x. | Amphibians | 0 | 30 | 87 | 0 | 0 | 117 |
| 4.y. | Fish | 0 | 0 | 0 | 1020 | 1000 | 2020 |
| 4.z. | TOTAL | 36759 | 35530 | 58218 | 125954 | 22748 | 279209 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 5.4 <br> Member Country of Council of Europe (but not EC) legislation <br> 2) | $\stackrel{5.5}{\text { Other legislation }}$ | 5.6 Any combination of 5.2/5.3/5.4/5.5 | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice |  |  |  |  | 68 | 54 | 122 |
| 5.b. | Rats |  | 80 |  |  |  |  | 80 |
| 5.c. | Guinea-Pigs |  |  |  |  | 406 | 54 | 460 |
| 5.d. | Hamsters |  |  |  |  |  |  | 0 |
| 5.e. | Other Rodents |  |  |  |  |  |  | 0 |
| 5.f. | Rabbits |  |  |  |  | 42 | 6 | 48 |
| 5.g. | Cats |  |  |  |  |  |  | 0 |
| 5.h. | Dogs |  |  |  |  |  |  | 0 |
| 5.i. | Ferrets |  |  |  |  |  |  | 0 |
| 5.j. | Other Carnivores |  |  |  |  |  |  | 0 |
| 5.k. | Horses, donkeys and cross breds |  |  |  |  |  |  | 0 |
| 5.1. | Pigs |  |  |  |  |  |  | 0 |
| 5.m. | Goats |  |  |  |  |  |  | 0 |
| 5.n. | Sheep |  |  |  |  |  |  | 0 |
| 5.0. | Cattle |  |  |  |  |  |  | 0 |
| 5.p. | Prosimians |  |  |  |  |  |  | 0 |
| 5.q. | New World Monkeys |  |  |  |  |  |  | 0 |
| 5.r. | Old World Monkeys |  |  |  |  |  |  | 0 |
| 5.s. | Apes |  |  |  |  |  |  | 0 |
| 5.t. | Other Mammals |  |  |  |  |  |  | 0 |
| 5.u. | Quail |  |  |  |  |  |  | 0 |
| 5.v. | Other birds |  |  |  |  |  | 15 | 15 |
| 5.w. | Reptiles |  |  |  |  |  |  | 0 |
| 5.x. | Amphibians |  |  |  |  |  |  | 0 |
| 5.y. | Fish |  |  |  |  |  |  | 0 |
| 5.z. | TOTAL | 0 | 80 | 0 | 0 | 516 | 129 | 725 |

Examples:
5.2 - France is testing due to a UK (or FR) specific requirement
5.3- UK is testing according to EC legislation
5.4 - Spain is testing due to a Hungarian requirement 5.5 - Sweden is testing due to a US specific requirement
5.6 - Germany is testing due to a Czech requirement (also an EC

Note: columns 5.2-5.5 refer to the legislation imposing that the test be carried out and not to the body which has issued the actual test method, guideline or protocol. a test required by French legislation and carried out in Belgium according to an ISO protocol must be coded as a national (FR) legislative requirement and be entered into column 5.2 in the tables submitted by Belgium

2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

## TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS

## Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 National legislation specific to a single EC Member State 1) | 6.3 <br> EC legislation <br> including European <br> Pharmacopoeia <br> (requirements) | 6.4 <br> Member Country of Council <br> of Europe (but not EC) <br> legislation <br> 2) | $\begin{gathered} 6.5 \\ \text { Other legislation } \end{gathered}$ | 6.6 Any combination of 6.2/6.3/ 6.4/ 6.5 | 6.7 <br> No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice | 842 |  |  |  |  | 1404 | 2246 |
| 6.b. | Rats | 4460 |  |  |  |  |  | 4460 |
| 6.c. | Guinea-Pigs |  |  |  |  |  |  |  |
| 6.d. | Hamsters |  |  |  |  |  |  |  |
| 6.e. | Other Rodents |  |  |  |  |  |  |  |
| 6.f. | Rabbits | 347 |  |  |  |  |  | 347 |
| $6 . \mathrm{g}$. | Cats |  |  |  |  |  |  |  |
| 6.h. | Dogs | 441 |  |  |  |  |  | 441 |
| 6.i. | Ferrets |  |  |  |  |  |  |  |
| 6.j. | Other Carnivores |  |  |  |  |  |  |  |
| 6.k. | Horses, donkeys and |  |  |  |  |  |  |  |
| 6.1. | Pigs |  |  |  |  |  |  |  |
| 6.m | Goats |  |  |  |  |  |  |  |
| 6.n. | Sheep |  |  |  |  |  |  |  |
| 6.0 | Cattle |  |  |  |  |  |  |  |
| 6.p | Prosimians |  |  |  |  |  |  |  |
| 6.q. | New World Monkeys |  |  |  |  | 12 |  |  |
| 6.r. | Old World Monkeys |  |  |  |  |  |  |  |
| 6.s. | Apes |  |  |  |  |  |  |  |
| 6.t. | Other Mammals |  |  |  |  |  |  |  |
| $6 . \mathrm{u}$ | Quail |  |  |  |  |  |  |  |
| 6.v | Other birds |  |  |  |  |  |  |  |
| 6.w | Reptiles |  |  |  |  |  |  |  |
| 6.x | Amphibians |  |  |  |  |  |  |  |
| 6.y | Fish | 7510 |  |  |  |  | 1157 | 8667 |
| 6.z. | TOTAL | 13600 |  |  |  | 12 | 2561 | 16173 |
| Examples: 6.2 - France is testing due to a UK (or FR) specific requirement <br>  6.3 - UK is testing according to EC legislation <br>  6.4 - Spain is testing due to a Hungarian requirement <br>  6.5 - Sweden is testing due to a US specific requirement <br>  6.6 - Germany is testing due to a Czech requirement (also an |  |  |  | Example: a test required by French legisla ISO protocol must be coded as a entered into column 6.2 in the ta |  | imposing that the tes tual test method, guid d carried out in Belgiv al (FR) legislative req bmitted by Belgium. | carried out and or protocol. ccording to an nent and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2 <br> Acute and sub-acute toxicity testing methods (including limit test) |  |  | 7.3 Skin irritation | 7.4 Skin sensitisatio n | $\begin{gathered} \hline 7.5 \\ \text { Eye } \\ \text { irritation } \end{gathered}$ | 7.6 Sub- chronic and chronic toxicity | $7.7$ <br> Carcinogenicity | 7.8 <br> Develop- <br> mental toxicity | 7.9 Muta- genicit y | $7.10$ <br> Reproductive toxicity | 7.11 <br> Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 7.12 \\ & \text { Other } \end{aligned}$ | $7.13$ <br> Total |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. |  |  |  | 462 |  | 1045 |  | 35 | 200 |  | 165 |  |  | 339 | 2246 |
| 7.b. | Rats |  | 265 | 3229 |  |  |  | 113 |  | 165 | 405 | 51 |  | 232 | 4460 |
| 7.c. | Guinea-Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.d. | Hamsters |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.e. | Other Rodents |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.f. | Rabbits |  |  | 36 |  |  |  |  |  | 263 |  | 48 |  |  | 347 |
| 7.g. | Cats |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.h. | Dogs |  |  | 383 |  |  |  | 40 |  |  |  |  |  | 18 | 441 |
| 7.i. | Ferrets |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.j. | Other Carnivores |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.k. | Horses, donkeys and cross breds |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.1. | Pigs |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.m. | Goats |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.n. | Sheep |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.0. | Cattle |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.p. | Prosimians |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.q. | New World Monkeys |  |  |  |  |  |  | 12 |  |  |  |  |  |  |  |
| 7.r. | Old World Monkeys |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.s. | Apes |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.t. | Other Mammals |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.u. | Quail |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.v. | Other birds |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.w. | Reptiles |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.x. | Amphibians |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 7.y. | Fish |  |  |  |  |  |  |  |  | 3570 |  | 2850 | 2112 | 135 | 8667 |
| 7.z. | TOTAL | 0 | 265 | 4110 | 0 | 1045 | 0 | 200 | 200 | 3998 | 570 | 2949 | 2112 | 724 | 16173 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products

| $8.1$ <br> Products | 8.2Acute and sub-acute toxicity testing <br> methods (including limit test) |  |  | 8.3 Skin irritation | 8.4 Skin sensitisatio n | 8.5 Eye irritation | 8.6 Sub- <br> chronic and chronic toxicity | 8.7 <br> Carcino genicity | 8.8 <br> Developmental toxicity | 8.9 Muta- genicit $y$ | 8.10 Reproductive toxicity | 8.11 <br> Toxicity <br> to aquatic vertebrates not included in other columns | $\begin{gathered} 8.12 \\ \text { Other } \end{gathered}$ | $\begin{gathered} \hline 8.13 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 8.a. Products/substances or devices for human medicine and dentistry and for veterinary medicine |  | 265 | 4110 |  |  |  | 165 | 200 | 428 | 446 | 99 |  | 589 | 6302 |
| 8.b. Products/substances used or intended to be used mainly in agriculture |  |  |  |  |  |  |  |  |  |  | 300 |  |  | 300 |
| 8.c. $\begin{aligned} & \text { Products/substances used or intended to } \\ & \text { be used mainly in industry }\end{aligned}$ |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.d. Products/substances used or intended to be used mainly in the household |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.e. Products/substances used or intended to be used mainly as cosmetics or toiletries |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.f. Products/substances used or intended to be used mainly as additives in food for human consumption |  |  |  |  |  |  |  |  |  |  | 1045 |  |  | 1045 |
| 8.g. Products/substances used or intended to be used mainly as additives in food for animal consumption |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.h. Potential or actual contaminants in the general environment which do not appear in other columns |  |  |  |  |  |  | 35 |  | 3570 | 124 | 2550 | 2112 | 135 | 8526 |
| 8.i. Other toxicological or safety evaluations |  |  |  |  |  |  |  |  |  |  |  |  |  | 0 |
| 8.j. TOTAL | 0 | 265 | 4110 | 0 | 0 | 0 | 200 | 200 | 3998 | 570 | 3994 | 2112 | 724 | 16173 |

## UNITED KINGDOM

## Statistical data submitted

The United Kingdom statistical data for 2005 were prepared, quality assured and submitted by the "Home Office".

Within the United Kingdom (UK), Great Britain (GB) and Northern Ireland (NI) publish separate, annual statistical reports based largely on the number of procedures started rather than numbers of animals used.The 2005 data collection process was $100 \%$ complete.

In accord with our established practice the UK figures presented here have been recompiled from the original data in terms of animal numbers for the classes of animal use recorded in the EU statistical tables. It should be noted that the UK also regulates, and the UK domestic statistical reports enumerate, animals bred for the maintenance of colonies of genetically modified or harmful mutant animals, and that category of animal use largely accounts for the differences in the figures in the original GB \& NI publications and those in this EU report.

## Comments of United Kingdom authorities

In the UK, just over 1.87 million animals were used for the first time in procedures started in 2005, a rise of 57,000 on the number reported for 2002.

1,463,565 (78\%) of the animals used were mice and rats.
Cold-blooded animals (fish, amphibia, and reptiles) accounted for 203,173 animals, $11 \%$ of the animals used.

Cats, dogs, equidae and non-human primates are accorded special protection in the UK and collectively amounted to 9,104 animals, $0.5 \%$ of the animals used -a reduction of 841 compared with 2002.

Non-human primates accounted for 3,115 animals, $0.16 \%$ of animals used -58 fewer than in 2002.
$99 \%$ of the animals that must be sourced from approved breeders or suppliers originated from UK registered breeding or supplying establishments. Less than $0.5 \%$ were sourced outside of EC or Council of Europe member countries.

974,046 animals (52\%) were used for fundamental biological studies, research and development relating to human medicine, dentistry and veterinary medicine.

Toxicological or other safety evaluation used 248,610 animals (13\%) - a reduction of 73,323 since 2002.

There was a marked reduction in the number of animals used to satisfy national legislation specific to a single member state, with the majority of the animal use ( $72 \%$ ) being to fulfil multinational regulatory requirements.

110,384 animals $(6 \%)$ were used for the production and quality control of products and devices for human medicine, dentistry or veterinary medicine - over 45,000 fewer than in 2002.

Approximately $40 \%$ of animals used received some form of anaesthesia. For the other animals the use of anaesthesia would have been deemed to increase the severity of the procedure.

As in 2002 no animals were used to evaluate the safety of either cosmetic products or cosmetic ingredients.

No animals were used in 2005 for monoclonal antibody production using the ascites method.

TABLE 1: NUMBER OF ANIMALS USED IN RELATION TO THEIR PLACE OF ORIGIN
Origin versus species

|  | $\begin{gathered} 1.1 \\ \text { Species } \end{gathered}$ | $\begin{gathered} 1.2 \\ \text { Total } \end{gathered}$ | 1.3 Animals coming from registered breeding or supplying establishments within the reporting country | 1.4 <br> Animals coming from elsewhere in the EC | 1.5 <br> Animals coming from Member Countries of the Council of Europe which are parties to the Convention ETS 123 (excluding EC Member States) | 1.6Animals coming from <br> other origins | 1.7 Re-used animals |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 1.a. | Mice (Mus musculus) | 1052064 | 1048052 | 690 | 40 | 3282 |  |
| 1.b. | Rats (Rattus norvegicus) | 411501 | 408104 | 1183 | - | 2214 |  |
| 1.c. | Guinea-Pigs (Cavia porcellus) | 28918 | 28918 | - | - | - |  |
| 1.d. | Hamsters (Mesocricetus ) | 3746 | 2219 | 1256 | 271 | - |  |
| 1.e. | Other Rodents (other Rodentia) | 8216 |  |  |  |  |  |
| 1.f. | Rabbits (Oryctolagus cuniculus) | 15523 | 15063 | 410 | 2 | 48 | 2315 |
| 1.g. | Cats (Felis catus) | 308 | 205 | 103 | - | - | 175 |
| 1.h. | Dogs (Canis familiaris) | 5373 | 4294 | 194 | - | 885 | 907 |
| 1.i. | Ferrets (Mustela putorius furo) | 1004 | 970 | - | - | 34 | 18 |
| 1.j. | Other Carnivores (other Carnivora) | 938 |  |  |  |  |  |
| 1.k. | Horses, donkeys and cross breds (Equidae) | 308 |  |  |  |  |  |
| 1.1. | Pigs (Sus) | 4127 |  |  |  |  |  |
| 1.m. | Goats (Capra) | 274 |  |  |  |  |  |
| 1.n. | Sheep (Ovis) | 11772 |  |  |  |  |  |
| 1.0. | Cattle (Bos) | 6306 |  |  |  |  |  |
| 1.p. | Prosimians (Prosimia) | - | - | - | - | - | - |
| 1.q. | New World Monkeys (Ceboidea) | 643 | 501 | 108 | 34 | - | 148 |
| 1.r. | Old World Monkeys (Cercopithecoidea) | 2472 | 135 | 6 | - | 2331 | 590 |
| 1.s. | Apes (Hominoidea) | - | - | - | - | - | - |
| 1.t. | Other Mammals(other Mammalia) | 2541 |  |  |  |  |  |
| 1.u. | Quail (Coturnix coturnix) | 140 | 140 | - | - | - |  |
| 1.v. | Other birds (other Aves) | 114860 |  |  |  |  |  |
| 1.w. | Reptiles (Reptilia) | 84 |  |  |  |  |  |
| 1.x. | Amphibians (Amphibia) | 10585 |  |  |  |  |  |
| 1.y. | Fish (Pisces) | 192504 |  |  |  |  |  |
| 1.z. | TOTAL | 1874207 |  |  |  |  |  |

 of those countries has to be used when filling in this column.

## Note 2: Only the white boxes need to be completed.

Note 3: The number of re-used animals in column 1.7 should be excluded from the total in the column 1.2

TABLE 2: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR SELECTED PURPOSES

|  | $\begin{gathered} 2.1 \\ \text { Species } \end{gathered}$ | 2.2 <br> Biological studies of a fundamenta 1 nature | 2.3 <br> Research and development of products and devices for human medicine and dentistry and for veterinary medicine (excluding toxicological and other safety evaluations counted in column 2.6) | 2.4 Production and quality control of products and devices for human medicine and dentistry | 2.5 Production and quality control of products and devices for veterinary medicine | 2.6 Toxicological and other safety evaluations (including safety evaluation of products and devices for human medicine and dentistry and for veterinary medicine) | 2.7 <br> Diagnosis of disease | 2.8Education and <br> training | $\begin{gathered} \hline 2.9 \\ \text { Other } \end{gathered}$ | $\begin{aligned} & \hline 2.10 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2.a. | Mice | 55660 | 92488 | 63461 | 18280 | 81113 | 8016 | 896 | 432150 | 1052064 |
| 2.b. | Rats | 115092 | 143212 | 4061 | - | 110005 | 10 | 1427 | 37694 | 411501 |
| 2.c. | Guinea-Pigs | 3235 | 11578 | 7396 | 1273 | 2890 | 448 | 118 | 1980 | 28918 |
| 2.d. | Hamsters | 1656 | 30 | 60 | 480 | 1304 | - | - | 216 | 3746 |
| 2.e. | Other Rodents | 5266 | 2794 | - | - | 40 | - | 2 | 114 | 8216 |
| 2.f. | Rabbits | 1488 | 768 | 338 | 990 | 8456 | 1737 | 32 | 1714 | 15523 |
| 2.g. | Cats | 237 | 71 | - | - | - | - | - | - | 308 |
| 2.h. | Dogs | 119 | 748 | 4 | - | 4248 | 15 | - | 39 | 5373 |
| 2.i. | Ferrets | 172 | 94 | 6 | - | - | 35 | 13 | 684 | 1004 |
| 2.j. | Other Carnivores | 502 | - | - | - | - | - | - | 436 | 938 |
| 2.k. | Horses, donkeys and cross breds | 38 | 31 | - | 50 | 25 | 68 | 8 | 88 | 308 |
| 2.1. | Pigs | 2046 | 445 | 36 | 716 | 541 | - | - | 343 | 4127 |
| 2.m. | Goats | 233 | 6 | - | - | 3 | 11 | - | 21 | 274 |
| 2.n. | Sheep | 5681 | 136 | - | 169 | 223 | 408 | 5 | 5150 | 11772 |
| 2.0. | Cattle | 4312 | 523 | - | 718 | 345 | 9 | - | 399 | 6306 |
| 2.p. | Prosimians | - | - | - | - | - | - | - | - | - |
| 2.q. | New World Monkeys | 114 | 86 | 8 | - | 334 | 16 | - | 85 | 643 |
| 2.r. | Old World Monkeys | 89 | 110 | - | - | 2257 |  | - | 16 | 2472 |
| 2.s. | Apes | - | - | - | - | - | - | - | - | - |
| 2.t. | Other Mammals | 1937 | - | - | - | 15 | - | - | 589 | 2541 |
| 2.u. | Quail | 140 | - | - | - | - | - | - | - | 140 |
| 2.v. | Other birds | 29119 | 687 | - | 5746 | 4000 | 2470 | 6 | 72832 | 114860 |
| 2.w. | Reptiles | 70 | - | - | - | 12 | - | - | 2 | 84 |
| 2.x. | Amphibians | 8943 | - | - | - | - | - | - | 1642 | 10585 |
| 2.y. | Fish | 106445 | 2275 | - | 6592 | 32799 | 163 | - | 44230 | 192504 |
| 2.z. | TOTAL | 642594 | 256082 | 75370 | 35014 | 248610 | 13406 | 2507 | 600624 | 1874207 |

TABLE 3: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Products versus species

|  | $\begin{gathered} 3.1 \\ \text { Species } \end{gathered}$ | 3.2 <br> Products/ substances or devices for human medicine and dentistry and for veterinary medicine | 3.3 <br> Products/ substances used or intended to be used mainly in agriculture | 3.4 <br> Products/ substances used or intended to be used mainly in industry | 3.5 <br> Products/ substances used or intended to be used mainly in the household | 3.6 <br> Products/ substances used or intended to be used mainly as cosmetics or toiletries | 3.7 <br> Products/ substances used or intended to be used mainly as additives in food for human consumption | 3.8 <br> Products/ substances used or intended to be used mainly as additives in food for animal consumption | 3.9 <br> Potential or actual contaminants in the general environment which do not appear in other columns | 3.10 <br> Other toxicological or safety evaluations | $\begin{aligned} & \hline 3.11 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 3.a. | Mice | 49965 | 3335 | 6955 | 21 | - | - | - | 3 | 20834 | 81113 |
| 3.b. | Rats | 70890 | 18134 | 10621 | - | - | - | - | 324 | 10036 | 110005 |
| 3.c. | Guinea-Pigs | 2366 | 120 | 128 | - | - | - | - | - | 276 | 2890 |
| 3.d. | Hamsters | 721 | 551 | 16 | - | - | - | - | - | 16 | 1304 |
| 3.e. | Other Rodents | - | 40 | - | - | - | - | - | - | - | 40 |
| 3.f. | Rabbits | 5378 | 1120 | 1742 | - | - | - | - | - | 216 | 8456 |
| 3.g. | Cats | - | - | - | - | - | - | - | - | - | - |
| 3.h. | Dogs | 4012 | 91 | 3 | - | - | - | - | - | 142 | 4248 |
| 3.i. | Ferrets | - | - | - | - | - | - | - | - | - | - |
| 3.j. | Other Carnivores | - | - | - | - | - | - | - | - | - | - |
| 3.k. | Horses, donkeys and cross breds | 25 | - | - | - | - | - | - | - | - | 25 |
| 3.1. | Pigs | 409 | 90 | - | - | - | - | - | - | 42 | 541 |
| 3.m. | Goats | - | 3 | - | - | - | - | - | - | - | 3 |
| 3.n. | Sheep | 213 | 10 | - | - | - | - | - | - | - | 223 |
| 3.0. | Cattle | 297 | 48 | - | - | - | - | - | - | - | 345 |
| 3.p. | Prosimians | - | - | - | - | - | - | - | - | - | - |
| 3.q. | New World Monkeys | 297 | - | - | - | - | - | - | - | 37 | 334 |
| 3.r. | Old World Monkeys | 1961 | - | - | - | - | - | - | - | 296 | 2257 |
| 3.s. | Apes | - | - | - | - | - | - | - | - | - | - |
| 3.t. | Other Mammals | 15 | - | - | - | - | - | - | - | - | 15 |
| 3.u. | Quail | - | - | - | - | - | - | - | - | - | - |
| 3.v. | Other birds | 1240 | 2620 | - | - | - | - | - | 131 | 9 | 4000 |
| 3.w. | Reptiles | - | - | - | - | - | - | - | - | 12 | 12 |
| 3.x. | Amphibians | - | - | - | - | - | - | - | - | - | - |
| 3.y. | Fish | 3326 | 6579 | 4398 | - | - | - | - | 16109 | 2387 | 32799 |
| 3.z. | TOTAL | 141115 | 32741 | 23863 | 21 | - | - | - | 16567 | 34303 | 248610 |

TABLE 4: NUMBER OF ANIMALS USED IN EXPERIMENTS FOR STUDIES ON HUMAN AND ANIMAL DISEASES
Main categories versus species

|  |  | 4.2 Human cardiovascular diseases | 4.3Human nervous and <br> mental disorders | 4.4 <br> Human cancer (excluding <br> evaluations of carcinogenic <br> hazards or risks) | 4.5 Other human diseases | 4.6 <br> Studies specific to animal diseases | $\begin{gathered} \hline 4.7 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 4.a. | Mice | 22260 | 99729 | 86802 | 459327 | 22392 | 690510 |
| 4.b. | Rats | 16176 | 145474 | 5694 | 187929 | 1464 | 356737 |
| 4.c. | Guinea-Pigs | 975 | 1884 | - | 23963 | 1564 | 28386 |
| 4.d. | Hamsters | - | 740 | 76 | 1707 | 639 | 3162 |
| 4.e. | Other Rodents | 38 | 4517 | 85 | 3470 | - | 8110 |
| 4.f. | Rabbits | 1005 | 99 | 63 | 9944 | 1337 | 12448 |
| 4.g. | Cats | - | 98 | - | 139 | 71 | 308 |
| 4.h. | Dogs | 466 | 3 | 10 | 4502 | 280 | 5261 |
| 4.i. | Ferrets | 102 | 140 | - | 749 | - | 991 |
| 4.j. | Other Carnivores | 2 | - | - | 500 | 403 | 905 |
| 4.k. | Horses, donkeys and cross breds | - | 12 | - | 94 | 192 | 298 |
| 4.1. | Pigs | 278 | 62 | - | 2205 | 1543 | 4088 |
| 4.m. | Goats | 31 | - | - | 232 | 8 | 271 |
| 4.n. | Sheep | 116 | 474 | - | 6244 | 4864 | 11698 |
| 4.0. | Cattle | 135 | 1788 | - | 2398 | 1914 | 6235 |
| 4.p. | Prosimians | - | - | - | - | - | - |
| 4.q. | New World Monkeys | 33 | 50 | - | 547 | - | 630 |
| 4.r. | Old World Monkeys | 41 | 76 | - | 2097 | - | 2214 |
| 4.s. | Apes | - | - | - | - | - | - |
| 4.t. | Other Mammals | 240 | 182 | - | 1697 | 15 | 2134 |
| 4.u. | Quail | - | 140 | - | - | - | 140 |
| 4.v. | Other birds | 1377 | 5456 | - | 25010 | 80509 | 112352 |
| 4.w. | Reptiles | - | 70 | - | 12 | - | 82 |
| 4.x. | Amphibians | 472 | 53 | 745 | 7673 | - | 8943 |
| 4.y. | Fish | - | 3282 | - | 105746 | 25538 | 134566 |
| 4.z. | TOTAL | 43747 | 264329 | 93475 | 846185 | 142733 | 1390469 |

TABLE 5: NUMBER OF ANIMALS USED IN PRODUCTION AND QUALITY CONTROL OF PRODUCTS AND DEVICES FOR HUMAN MEDICINE AND DENTISTRY AND FOR VETERINARY MEDICINE

Regulatory requirements versus species

|  | $\begin{gathered} 5.1 \\ \text { Species } \end{gathered}$ | 5.2 National legislation specific to a single EC Member State 1) | 5.3 EC legislation including European Pharmacopoeia (requirements) | 5.4 <br> Member Country of Council <br> of Europe (but not EC) <br> legislation <br> 2) | 5.5 Other legislation | $5.6$ <br> Any combination of 5.2/5.3/5.4/ 5.5 | 5.7 No regulatory requirements | $\begin{gathered} \hline 5.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 5.a. | Mice | 1924 | 6000 | - - | 136 | 66574 | 7107 | 81741 |
| 5.b. | Rats | - | 1920 | - | - | 567 | 1574 | 4061 |
| 5.c. | Guinea-Pigs | 5711 | 1399 | - | 122 | 1137 | 300 | 8669 |
| 5.d. | Hamsters | - | 480 | - | - | - | 60 | 540 |
| 5.e. | Other Rodents | - | - | - | - | - | - | - |
| 5.f. | Rabbits | 116 | - | - | - | 1202 | 10 | 1328 |
| 5.g. | Cats | - | - | - | - | - | - | - |
| 5.h. | Dogs | - | - | - | - | - | 4 | 4 |
| 5.i. | Ferrets | - | - | - | - | - | 6 | 6 |
| 5.j. | Other Carnivores | - | - | - | - | - | - | - |
| 5.k. | Horses, donkeys and cross breds | - | - | - | - | 50 | - | 50 |
| 5.1. | Pigs | 24 | 716 | - | - | - | 12 | 752 |
| 5.m. | Goats | - | - | - | - | - | - | - |
| 5.n. | Sheep | - | 98 | - | - | 71 | - | 169 |
| 5.0. | Cattle | 49 | 265 | - | - | 352 | 52 | 718 |
| 5.p. | Prosimians | - | - | - | - | - | - | - |
| 5.q. | New World Monkeys | - | - | - | - | - | 8 | 8 |
| 5.r. | Old World Monkeys | - | - | - | - | - | - | - |
|  | Apes | - | - | - | - | - | - | - |
|  | Other Mammals | - | - | - | - | - | - | - |
| 5.u. | Quail | - | - | - | - | - | - | - |
| 5.v. | Other birds | - | 68 | - | - | 5185 | 493 | 5746 |
| 5.w. | Reptiles | - | - | - | - | - | - | - |
| 5.x. | Amphibians | - | - | - | - | - | - | - |
| 5.y. | Fish | - | 2621 | - | - | 3971 | - | 6592 |
| 5.z. | TOTAL | 7824 | 13567 | - | 258 | 79109 | 9626 | 110384 |
| $\begin{array}{ll}\text { Examples: } & 5.2 \text { - France is testing due to a UK (or FR) specific requirement } \\ & 5.3 \text { - UK is testing according to EC legislation } \\ & 5.4 \text { - Spain is testing due to a Hungarian requirement } \\ & 5.5 \text { - Sweden is testing due to a US specific requirement } \\ & 5.6 \text { - Germany is testing due to a Czech requirement (also an EC }\end{array}$ |  |  |  | Example: a test required by French legislati |  | imposing that the test ual test method, guide d carried out in Belgi al (FR) legislative req bmitted by Belgium. | carried out and or protocol. ccording to an nent and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta, Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 6: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Regulatory requirements versus species

|  | $\begin{gathered} 6.1 \\ \text { Species } \end{gathered}$ | 6.2 National legislation specific to a single EC Member State 1) | 6.3 EC legislation including European Pharmacopoeia (requirements) | 6.4 Member Country of Council of Europe (but not EC) legislation 2) | 6.5 Other legislation | 6.6 Any combination of $6.2 / 6.3 / 6.4 / 6.5$ | $\quad 6.7$ No regulatory requirements | $\begin{gathered} \hline 6.8 \\ \text { Total } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 6.a. | Mice | 566 | 8683 | - - | 1921 | 57004 | 12939 | 81113 |
| 6.b. | Rats | 1000 | 3862 | - | 3869 | 92289 | 8985 | 110005 |
| 6.c. | Guinea-Pigs | 4 | 165 | - | 256 | 2076 | 389 | 2890 |
| 6.d. | Hamsters | - | - | - | - | 1022 | 282 | 1304 |
| 6.e. | Other Rodents | - | - | - | - | - | 40 | 40 |
| 6.f. | Rabbits | 29 | 2114 | - | 539 | 5662 | 112 | 8456 |
| 6.g. | Cats | - | - | - | - | - | - | - |
| 6.h. | Dogs | - | 24 | - | - | 4051 | 173 | 4248 |
| 6.i. | Ferrets | - | - | - | - | - | - | - |
| 6.j. | Other Carnivores | - | - | - | - | - | - | - |
| 6.k. | Horses, donkeys and cross breds | - | - | - | - | 25 | - | 25 |
| 6.1. | Pigs | - | 181 | - | - | 305 | 55 | 541 |
| 6.m. | Goats | - | - | - | - | 3 | - | 3 |
| 6.n. | Sheep | - | 36 | - | - | 181 | 6 | 223 |
| 6.0. | Cattle | 4 | 151 | - | - | 178 | 12 | 345 |
| 6.p. | Prosimians | - | - | - | - | - | - | - |
| 6.q. | New World Monkeys | - | - | - | - | 297 | 37 | 334 |
|  | Old World Monkeys | - | - | - | - | 2207 | 50 | 2257 |
| 6.s. | Apes | - | - | - | - | - | - | - |
| 6.t. | Other Mammals | - | 15 | - | - | - | - | 15 |
|  | Quail | - | - | - | - | - | - | - |
| 6.v. | Other birds | 50 | 950 | - | 522 | 2306 | 172 | 4000 |
| 6.w. | Reptiles | 12 | - | - | - | - | - | 12 |
| 6.x. | Amphibians | - | - | - | - | - | - | - |
| 6.y. | Fish | 3581 | 7148 | - | 1144 | 15110 | 5816 | 32799 |
| 6.z. | TOTAL | 5246 | 23329 | - | 8251 | 182716 | 29068 | 248610 |
| Examples: 6.2 - France is testing due to a UK (or FR) specific requirement <br>  6.3 - UK is testing according to EC legislation <br>  6.4 - Spain is testing due to a Hungarian requirement <br>  6.5 - Sweden is testing due to a US specific requirement <br>  6.6 - Germany is testing due to a Czech requirement (also an EC |  |  |  | Note: columns $6.2-$ <br> not to the bod <br> Example: <br>  <br>  <br>  <br>  <br>  <br>  <br>  <br> ISO test require <br> entered into | 5 refer to the legis which has issued t by French legislatio ust be coded as a n umn 6.2 in the tab | imposing that the test tual test method, guide nd carried out in Belgi al (FR) legislative req bmitted by Belgium. | carried out and or protocol. ccording to an ment and be |  |


2) Member Countries of Council of Europe (non-EC): Albania, Andorra, Bulgaria, Croatia, Cyprus, Czech Rep., Estonia, Hungary, Iceland, Latvia, Liechtenstein, Lithuania, Malta Moldova, Norway, Poland, Romania, Russia, San Marino, Slovakia, Slovenia, Switzerland, 'the former Yugoslav Rep. of Macedonia', Turkey, Ukraine

TABLE 7: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus species

| $\begin{gathered} 7.1 \\ \text { Species } \end{gathered}$ |  | 7.2Acute and sub-acute toxicity testing methods (including limit test) |  |  | $\begin{gathered} 7.3 \\ \text { Skin } \\ \text { irritation } \end{gathered}$ | 7.4 Skin Sensitisatio n | $\begin{gathered} \hline 7.5 \\ \text { Eye } \\ \text { irritation } \end{gathered}$ | 7.6 Sub- chronic and chronic toxicity | 7.7 Carcinogenicity | 7.8 Developmental toxicity | $\begin{gathered} 7.9 \\ \text { Muta- } \\ \text { genicit } \\ \text { y } \end{gathered}$ |  | 7.11 Toxicity to aquatic vertebrates not included in other columns | $\begin{aligned} & \hline 7.12 \\ & \text { Other } \end{aligned}$ | $\begin{aligned} & \hline 7.13 \\ & \text { Total } \end{aligned}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 7.a. | Mice | 6784 | 384 | 7497 | 6 | 2496 |  | 4424 | 7549 | 769 | 3247 |  |  | 47957 | 81113 |
| 7.b. | Rats | 3636 | 2309 | 30789 | - |  | - | 11778 | 8654 | 4556 | 5565 | 25216 |  | 17502 | 110005 |
| 7.c. | Guinea-Pigs | 217 |  | 86 | 12 | 278 | - | - | - |  | - | - |  | 2297 | 2890 |
| 7.d. | Hamsters |  |  | 482 | - | - | - | - | - | - | - | - | - | 822 | 1304 |
| 7.e. | Other Rodents | - |  |  | - | - | - | - | - | - | - | - | - | 40 | 40 |
| 7.f. | Rabbits | - | 12 | 532 | 1302 | - | 837 | 244 | - | 3141 | - | 123 | - | 2265 | 8456 |
| 7.g. | Cats | - | - | - | - | - | - | - | - | - | - | - | - | - |  |
| 7.h. | Dogs | - | - | 2279 | - | - | - | 1541 | - | - | - | - | - | 428 | 4248 |
| 7.i. | Ferrets | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 7.j. | Other Carnivores | - | - | - | - | - | - | - | - | - | - | - | - |  |  |
| 7.k. | Horses, donkeys and cross breds | - | - | - | - | - | - | - | - | - | - | - | - | 25 | 25 |
| 7.1. | Pigs | - | - | 52 | - | - | - | - | - | - | - | - | - | 489 | 541 |
| 7.m. | Goats | - | - |  | - | - | - | - | - | - | - | - | - | 3 | 3 |
| 7.n. | Sheep | - | - | 24 | - | - | - | - | - | - | - | - | - | 199 | 223 |
| 7.0. | Cattle | - | - | 39 | - | - | - | - | - | - | - | - | - | 306 | 345 |
| 7.p. | Prosimians | - |  | - | - | - | - | - | - | - | - | - | - |  |  |
| 7.q. | New World Monkeys | - | 13 | 112 | - | - | - | 155 | - | - | - | - | - | 54 | 334 |
| 7.r. | Old World Monkeys | - | - | 1035 | - | - | - | 838 | - | - | - | - | - | 384 | 2257 |
| 7.s. | Apes | - | - | - | - | - | - | - | - | - | - | - |  |  |  |
| 7.t. | Other Mammals | - | - | - | - | - | - | - | - | - | - | - | - | 15 | 15 |
| 7.u. | Quail | - |  |  | - | - | - | - | - | - | - | - | - | - |  |
| 7.v. | Other birds | 920 | 140 | 400 | - | - | - | - | - | - | - | - | - | 2540 | 4000 |
| 7.w. | Reptiles | - | - | - | - | - | - | - | - | - | - | - | - | 12 | 12 |
| 7.x. | Amphibians | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 7.y. | Fish | 9192 | 7157 | 6963 | - | - | - | 752 | - | - | 226 | 710 | - | 7799 | 32799 |
| 7.z. | TOTAL | 20749 | 10015 | 50290 | 1320 | 2774 | 837 | 19732 | 16203 | 8466 | 9038 | 26049 | - | 83137 | 248610 |

TABLE 8: NUMBER OF ANIMALS USED IN TOXICOLOGICAL AND OTHER SAFETY EVALUATIONS
Types of tests versus products



[^0]:    OJ L 358, 18.12.1986, p. 1
    COM (94) 195 final COM (1999) 191 final
    COM (2003) 19 final
    COM (2005) 7 final

[^1]:    $6 \quad$ OJ C 331, 23.12.86, p. 2.

[^2]:    ■Specific animals diseases \%
    $\square$ Other human diseases \%
    EHuman cancer (excl. evaluation of carcino hazards) \%
    © Human nervous and mental disorder \%
    $\square$ Human Cardiovascular diseases\%

[^3]:    7 UL RS - Uradni list Republike Slovenija - Official Gazette of the Republic of Slovenia

